IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ICU MEDICAL, INC.,	)	
	)	
Plaintiff,	)	Civil .Action. No. 07- 00468-JJF
	)	
v.	)	
	)	
RYMED TECHNOLOGIES, INC.,	)	
Defendant.	)	

DECLARATION OF KATHARINE L. ALTEMUS IN SUPPORT OF RYMED TECHNOLOGIES, INC.'S MOTION TO TRANSFER VENUE PURSUANT TO 28 U.S.C. § 1404(a)

1. I am an attorney at law licensed to practice in the State of California and an associate in the law firm of Howrey LLP, attorneys for defendant RyMed Technologies, Inc ("RyMed"). The matters set forth in this declaration are based upon my personal knowledge, and if called as a witness, I could and would testify competently to those facts.

2. Attached as Exhibit A is a true and correct copy of Judge Mariana R. Pfaelzer's July 17, 2006 Claim Construction Order in the Central District of California action *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*, Case No. CV-04-00689-MRP (VBKx).

3. Attached as Exhibit B is a true and correct copy of Judge Mariana R. Pfaelzer's August 24, 2006 Judgment Granting Defendant Alaris Medical Systems, Inc.'s Motion for Partial Summary Judgment of Noninfringement of "Spike" Claims in the Central District of California action *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*, Case No. CV-04-00689-MRP (VBKx).

4. Attached as Exhibit C is a true and correct copy of Judge Mariana R. Pfaelzer's February 21, 2007 Judgment of Invalidity of Plaintiff ICU's Spikeless Claims Under 35

U.S.C. § 112, ¶¶ 1 & 2 in the Central District of California action *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*, Case No. CV-04-00689-MRP (VBKx).

5. Attached as Exhibit D is a true and correct copy of Judge Mariana R. Pfaelzer's September 21, 2007 Final Judgment in the Central District of California action *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*, Case No. CV-04-00689-MRP (VBKx).

6. Attached as Exhibit E is a true and correct copy of Judge Mariana R. Pfaelzer's September 14, 2007 Order Granting ICU's Motion For Summary Judgment of Noninfringement in the Central in the Central District of California action *Medegen MMS, Inc., v. ICU Medical, Inc.*, Case No. SA-CV-06-619-MRP (AN).

7. Attached as Exhibit F is a true and correct copy of Judge Charles R. Breyer's July 17, 2006 Claim Construction Order in the Northern District of California action *ICU Medical, Inc. v. B. Braun Medical, Inc.*, Case No. C01-3202-CRB.

8. Attached as Exhibit G is a true and correct copy of Judge Charles R. Breyer's July 17, 2006 Stipulated Order of Dismissal With Prejudice of the Northern District of California action *ICU Medical, Inc. v. B. Braun Medical, Inc.*, Case No. C01-3202-CRB.

9. Attached as Exhibit H is a true and correct copy of RyMed's Complaint for Injunctive Relief and Damages (Case No. SACV07-1199-DOC (MLGx)) filed on October 10, 2007 in the United States District Court for the Central District of California.

10. Attached as Exhibit I is a true and correct copy of RyMed's Notice of Related Cases and Notice of Pendency of Other Action or Proceedings filed with the Central District of California on October 10, 2007.

11. Attached as Exhibit J is a true and correct copy of *Cashedge, Inc. v. Yodlee, Inc.*, No. Civ.A.06-170-JJF, 2006 WL 2038504 (D. Del. 2006).

12. Attached as Exhibit K is a true and correct copy of a page from ICU Medical's website, http://www.icumedical.com/about.asp.

13. Attached as Exhibit L is a true and correct copy of "Table C-5. Median Time Intervals From Filing to Disposition of Civil Cases Terminated, by District and Method

of Disposition, During the 12-Month Period Ending December 31, 2006", published by the Office of Judges Programs (Statistics Division) of the Administrative Office of the United States Courts at http://www.uscourts.gov/stats/dec06/index.html.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Katharine L. Altemus

Executed in East Palo Alto, CA, October 11, 2007

CERTIFICATE OF SERVICE

The undersigned counsel certifies that, on October 11, 2007, he electronically filed the foregoing document with the Clerk of the Court using CM/ECF, which will send automatic notification of the filing to the following:

Richard L. Horwitz, Esquire
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The undersigned counsel further certifies that, on October 11, 2007, copies of the foregoing document were sent by email and hand to the above local counsel and by email and first class mail to the following non-registered participant:

James Pooley, Esquire
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/s/ Richard D. Kirk (rk0922)
Richard D. Kirk

EXHIBIT A

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

ICU MEDICAL, INC., Plaintiff, v. ALARIS MEDICAL SYSTEMS, INC., Defendant.	Case File No. SA CV 04-0689 MRP (VBKx) CLAIM CONSTRUCTION ORDER

I. Introduction

In this case, plaintiff ICU Medical, Inc., a Delaware corporation ("ICU"), alleges infringement of four of its patents by defendant Alaris Medical Systems, Inc., a Delaware corporation ("Alaris"): United States Patent Nos. 5,685,866 ("the '866 patent"), 5,873,862 ("the '862 patent"), 6,572,592 ("the '592 patent") and 6,682,509 ("the '509 patent"). All four patents relate to a medical device - a needle-free valve which, when opened, can deliver drugs, blood and other fluids to and from a

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patient through intravenous tubing. Although the four patents in suit differ from one another in terms of scope and specific claim language, they all relate to this same technology, claim priority from the same original application, and share a common specification (the "Common Specification"). Before the court is the task of construing certain disputed claim terms of the patents in suit.

In arriving at the claim constructions set forth herein, the court has reviewed and considered various briefs submitted by the parties, including those submitted by both parties in connection with Alaris's motion for Partial Summary Judgment of Noninfringement of "Spike" Claims, as well as those submitted in connection with this Claim Construction Order ("Order"). On June 21 and 22, 2006, a Markman hearing was held in the matter, and the court heard extensive oral argument from the parties with respect to the terms construed in this Order.

II. Background

In June of 2004, ICU filed this lawsuit against Alaris, initially alleging that Alaris's SmartSite® Valve and SmartSite® Plus Valve infringe ICU's '509 patent. ICU asserted only the '509 patent, which the parties characterize as "spike-less" because its claims, unlike those of the '862, '866 and '592 patents, do not recite a "spike" element. Although the SmartSite® Valve had been on the market since 1996, immediately upon the filing of this lawsuit ICU also filed an ex parte application for a temporary restraining order and order to show cause why Alaris should not be preliminarily enjoined from

making, using and selling SmartSite Valves. On July 30, 2004, Judge Stotler issued an Order Denying Plaintiff's Motion for a Preliminary Injunction and Findings of Fact and Conclusions of Law (the "July 2004 Order"), which denied ICU's application, and which construed, as conclusions of law, three of the terms at issue in the present Order: "preslit"; "into an axially compressed state"; and "returning to an axially decompressed state". Upon denial of its preliminary injunction application, ICU subsequently amended its complaint to add claims for infringement of its '862, '866 and '592 "spike" patents. In September of 2005, Alaris filed a Motion for Partial Summary Judgment of Noninfringement of "Spike" Claims, which seeks the dismissal of those claims from the more recently added patents reciting a "spike" element. That motion is pending before this court.

III. Legal Standard

"The words of a [patent] claim are generally given their ordinary and customary meaning," i.e. "the meaning that the term would have to a person of ordinary skill in the art in question ... as of the [patent's] effective filing date." Phillips v. AWH Corp., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005)(en banc). The patent specification is central to a determination of "the meaning of a claim term as it is used by the inventor in the context of the entirety of his invention[.]" Comark Comm'ms v. Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998). The patent specification "is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the

single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315 (quoting Vitrioncs Corp. V. Conceptronic, Inc. 90 F.3d 1576, 1582 (Fed. Cir. 1996). "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention [in the specification] will be, in the end, the correct construction." *Id.* at 1316 (quoting Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998). Although a patent claim may at times contain terms that do not appear in the specification, all "terms and phrases used in the claims must find clear support or antecedent basis in the [specification] so that the meaning of the terms in the claims may be ascertainable by reference to the [specification]." Tandon Corp. V. U.S.I.T.C., 831 F. 2d 1017, 1024 (Fed. Cir. 1987); see Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997).

IV. Claim Construction

A. "Spike"

The term "spike" appears in the claims recited in the '592, '862 and '866 patents, and throughout the Common Specification. Alaris proposes that the term "spike" be defined as: "An elongated structure having a pointed tip for piercing the seal. The pointed tip may be sharp or slightly rounded." ICU proposes the broader definition, "an upward projection."

In terms of its focus on a pointed tip and the purpose of piercing, the definition proposed by Alaris comports more closely with the ordinary meaning of the word "spike." However, as *Phillips* instructs, in construing a disputed term the court must

look to the specification to see whether a different or more specific meaning is given to the term therein. In fact, the specification repeatedly and uniformly describes the spike as a pointed instrument for the purpose of piercing a seal inside the valve. For example, under the section entitled "Background of the Invention," the Common Specification states that "[t]his invention relates to ... [a] two-way valve ... which includes a seal which, upon being compressed by the medical implement, is pierced to open the valve." '862 Patent at 1:18-25.[1] Under the section entitled "Summary of the Invention," the Common Specification states that "[a] two-way valve is employed utilizing a reusable seal that may be repeatedly pierced by an enclosed, protected, non-metallic spike rather than an exposed needle." Id. at 2:40-43. Under the section entitled "Operation," the Common Specification states that the "nose of the medical implement is inserted into the valve ..., pushing the nose against the seal to compress the seal sufficiently to allow the tip of the spike to pierce the seal ..." Id. at 14:67-71. Furthermore, all of the figures in the Common Specification that depict a spike portray it as elongated and pointed, and the two figures that show an activated valve show the spike piercing the seal. Nowhere in the Common Specification is piercing described as optional, or is any non-piercing item described as a spike. The Summary of the Invention also states that the "tip [of the spike] may be sharp or slightly rounded." Id. at 3:10.

[1]Except where otherwise noted, all references herein to the Common Specification shall be to the '862 patent.

Nevertheless, ICU contends that the Common Specification discloses a wider array of possible spikes, of which the pointed piercing version is only one, albeit the preferred, embodiment. However, ICU's position finds little support in the Common Specification. ICU argues, for example, that claim 1 of the '866 patent, which recites "a spike having a tip, at least one hole located at or near said tip," describes a spike that is flat on top instead of being pointed. '866 Patent at 15:36-37. But Alaris's definition, which includes the sharp or slightly rounded language from the Common Specification, does allow for the possibility of a hole at the tip of the spike. Moreover, as Alaris notes, spikes featuring an angled tip allowing for a hole at the end while still having an acute tip were well-known at the time the original patents were filed in the early 1990's.

ICU devotes considerable attention to a single instance in the Common Specification in which the preferable distance from the spike tip to the lip of the housing is said to be approximately from 0.525" to 0.1". '862 Patent at 8:28-29. According to ICU, focusing on the longer end of this range, the Common Specification discloses a short, "stubby" spike that would be incapable of piercing or even reaching the seal. This argument fails for three reasons. First, in the context of a patent that repeatedly and consistently describes and portrays the operation of the patented device in terms of the piercing function of the spike, it is not reasonable to expect that even a person skilled in the art would be able to extrapolate from a single reference to a particular dimensional range a spike of a completely different purpose than that otherwise disclosed

throughout the patent. Second, even if one were able to extrapolate the short, non-piercing spike from the reference to this dimensional range, it is not at all clear how such a spike would operate or function in the context of the device disclosed. Finally, ICU's extrapolation of a short, non-piercing spike from the 0.525" to 0.1" range conflicts with another statement in the Common Specification, only two sentences later: "The spike tip is thus embedded in the seal cap prior to use or may be approximately 0.025" distal the seal cap when the valve is in the closed position." Id. at 8:21-24. As Alaris correctly points out, the only way to reconcile the so-called short spike with the 0.025" distal requirement would be for the seal cap itself to be at the longer end of its range disclosed in the Common Specification, thereby closing the gap between the spike and the seal and preserving the critical piercing function of the spike. The Common Specification does not disclose an unpointed and/or non-piercing spike.

ICU also draws attention to dependent claim 13 of the '592 patent, which recites, in relevant part, that the end of the spike 'is pointed so that it can pierce [the] seal." '592 Patent at 16:44-45. It argues that because this dependent claim recites the concepts of pointed and piercing, those concepts cannot be part of the proper construction of the term "spike" under the doctrine of claim differentiation. However, these concepts are not the only limitations contained in claim 13, which also requires that the end of the spike "enter into a portion of [the] medical implement when said medical implement is connected to [the] valve." Id. at 16:45-47. Because "pointed" and "piercing"

are not the only differences distinguishing dependent claim 13, the claim would not be rendered superfluous by including these concepts in the construction of "spike." See, e.g., Kraft Foods Inc. v. Int'l Trading Co., 203 F.3d 1362, 1368 (Fed. Cir. 2000) ("[T]hat the claims are presumed to differ in scope does not mean that every limitation must be distinguished from its counterpart in another claim, but only that at least one limitation must differ."). Moreover, dependent claim 13 was only added to the '592 patent in 2001, years after the filing date of the original patents, the issuance of the '866 and '862 patents, and the introduction of the allegedly infringing Alaris products.

The Common Specification clearly and uniformly describes a spike as having a pointed tip and being for the purpose of piercing the seal. Accordingly, the court finds that the proper construction for the term "spike" is "an elongated structure having a pointed tip for piercing the seal, which tip may be sharp or slightly rounded."

B. "Preslit Orifice"/"Seal Being Preslit"

Either or both of the terms "preslit orifice" and "seal being preslit" appear in claims recited in the '509, '592 and '862 patents, although neither term or any variation thereof appears in the Common Specification. Alaris proposes the following definition for these terms: "an opening that is cut in the seal before the seal is axially compressed." ICU in turn proposes the following definition: "an opening made or formed beforehand."

ICU added the "preslit" terms to its patent claims several years after filing the original application from which the Common Specification derives, and as such the word "preslit" does not appear in the Common Specification. However, every claim term must have an antecedent basis in the specification. See Tandon, 831 F. 2d at 1024; Lockwood, 107 F.3d at 1572 ("[A]ll the limitations must appear in the specification.").

The seal disclosed in ICU's original 1991 application contained no orifice at all until punctured by the spike during use. However, in 1992 ICU added new matter to the Common Specification containing various references to the term "precut". For example, the following references to precutting were added to the Summary of the Invention: "[t]he proximal end of the seal may be precut to form a tiny orifice therein that allows the tip of the spike to pass therethrough easily upon compression of the seal"; and "[t]ypically, the pressure responsive element is a section of the seal having an entryway into a precut orifice." '862 Patent at 4:3-6, 4:49-51 (emphasis added). Under the "Detailed Description of the Preferred Embodiment" section, the Common Specification states that "[p]rior to the use of the valve 10, it is preferable that the seal caps 40 or 92 be pierced centrally by a steel needle in the axial direction, precutting the seal to provide the slit 11 in order to allow for more rapid decompression and reformation of the seal upon piercing by the spike." Id. at 14:3-8 (emphasis added). These and other similar references to "precutting" are the only antecedent bases in the specification for "preslit", making clear that the term refers to cutting of the seal prior to axial compression, i.e., before

activation of the valve. This meaning also comports with the ordinary meanings of the component prefix "pre-" and word "slit." The court thus agrees with Judge Stotler's July 2004 Order that ICU's proposed construction, which would encompass any opening in the seal, however made, finds no support in the Common Specification. See July 2004 Order at Sec. III, ¶¶13-22.

The court therefore finds that the proper construction for the term "preslit orifice" is "an opening that is cut in the seal before the seal is axially compressed," and that the proper construction for "being preslit" is "having had an opening cut in the seal before the seal was axially compressed."

C. "Compressed State/Position" and "Decompressed State/Position"

The terms "compressed state" or "compressed position" and "decompressed state" or "decompressed position" appear in different forms in all four patents in suit. The Common Specification and the earlier issued '866 and '862 patents use the term "state," whereas the more recently issued '562 and '509 patents contain claims that employ the term "position." Although the parties have agreed that "state" and "position" should be construed consistently with one another, Alaris emphasizes "state" and ICU emphasizes "position" in their respective proposed constructions. The patents also use the terms "uncompressed" and "decompressed," apparently interchangeably, and the court will treat these words as synonymous for purposes of claim construction.

The parties disagree on the precise claim language to be construed. Alaris urges the court to construe the term "into a

compressed state" as "from a state (i.e condition) of no axial compression to a state of axial compression" and the term "returning to a decompressed state" as "returning to a state (i.e. condition) of no axial compression." ICU urges the court to construe the term "compressed position" as "the position of the seal when it is under axial compression from a medical implement and opens the valve" and the term "decompressed position" as the position of the seal when it not under axial compression from a medical implement and closes the valve." Because the words "into a" and "returning to a" from the claim language are not technical or obscure in their meaning, the court will follow ICU's lead and restrict its construction to "compressed position/state" and "decompressed position/state."

As noted above, although the parties agree that "state" and "position" should be construed similarly, they disagree over which word better captures the proper manner of viewing the role of axial compression in the claim language. Alaris, in focusing on the word "state," attempts to define compression in terms of the condition of the seal, i.e., either under axial compression or not. ICU, in focusing on the word "position," highlights the actual position of the seal and attempts to incorporate into the definitions the source of the compression, i.e. a medical implement, and the status of the valve, i.e. open or closed. A plain reading of the claim language itself makes clear that there is no need to import the source and valve status limitations into the construction of these terms, because they are already present in the claim language itself. For example, claim 1 of the '862 patent requires a seal that moves distally "into a compressed

state upon insertion of the delivery end of the medical implement ... and returning to a decompressed state upon removal of said delivery end from said opening..." Claim 1 goes on to describe the device in terms of "pushing said delivery end into the cavity to compress said seal sufficiently to allow the fluid to flow from said medical implement through [the] valve to the patient." Id. at 15:38-43 and 15:54-56. Both the concept of the medical implement as the source of compression and the concept of the valve being opened as a result of the compression are already included in the applicable claim language and thus do not need to be included in the construction of compression; indeed, to do so would render certain portions of the claim language superfluous or redundant.

Furthermore, the "into a" and "returning to a" language preceding the respective terms under construction make clear that what is at issue in the use of the terms "compressed state/position" and "decompressed state/position" in the claim language is best understood as referring to the condition of the seal, irrespective of the source or purpose of the compression. As Judge Stotler concluded in the July 2004 Order,

> ... to move into an axially compressed state the claimed seal must first start in a state in which it is not axially compressed. Logically, the claim language describing the seal as "returning to an axially decompressed state" must then mean that the seal returns to the original state of no compression from which it moved initially."

July 2004 Order at Sec. III, ¶27. Nothing in this claim language discloses or suggests any intermediate condition of relative or partial compression.

Every claim term must have an antecedent basis in the specification. See Tandon, 831 F. 2d at 1024; Lockwood, 107 F.3d at 1572. Here, the antecedent basis in the Common Specification for both "state" and "position" is "state," and the use of the term in the Common Specification confirms that the terms in question are best understood as referring to the condition of the seal. As an example, the Summary of the Invention mirrors the claim language in describing the seal as moving "into a compressed state upon insertion of the tip of the medical implement into the opening and returns to a decompressed state upon removal of the tip." Id. at 3:32-35. The Common Specification further states that "[the application of pressure on the syringe ... creates pressure on [the] seal cap," thereby suggesting that the seal was not initially under any pressure at all. Id. at 9:1-3. The Common Specification thus supports a straightforward reading of the claim language that suggests that "compressed state/position" and "decompressed state/compression" are best understood in terms of the presence or absence of axial compression.

The proper construction of "compressed state/position" is thus "a state (i.e. condition) of axial compression," and the proper construction of "decompressed state/position" is thus "a state (i.e. condition) of no axial compression."

D. "Fills Essenially Completely"

Alaris's proposed claim construction for this term is "fills almost entirely a portion of the cavity adjacent to the opening

to prevent fluid from leaking between the seal and the wall structure." At the Markman hearing in connection with this Order, attorneys for ICU indicated that they were amenable to this definition provided that the words "fills almost entirely" be replaced with "fills all of or almost entirely," and the word "swabbing" be inserted before the word "fluid." To the court's knowledge, no final agreement was reached between the parties. Nevertheless, the court will use the proposed ICU changes to the Alaris definition as a basis for discussing the construction of the claim.

The issue with respect to ICU's first proposed change is easily resolved. The words "essentially completely," while embracing a seal that allows for a slight gap between the seal and the wall so long as leakage is prevented, certainly does not foreclose the possibility of a complete seal. As to ICU's second proposed change, while swabbing fluid is likely to be the main concern in terms of leakage, the court finds no compelling reason why the seal function should not - and in fact would not - also apply to blood, pharmaceuticals, water, or any other fluid matter.

The proper construction of "fills essentially completely" is thus "fills all of or almost entirely a portion of the cavity adjacent to the opening to prevent fluid from leaking between the seal and the wall structure."

E. "Bearing Against Said Wall Structure Near Said Opening to Seal Said Opening"

Alaris proposes the following definition for this claim

term: "the seal is situated in contact with the wall structure [of the housing] near the opening of the proximal end of the housing to make the opening fluid tight." ICU in turn proposes the following definition: "the seal presses against the wall structure near the opening to prevent leakage of fluid into the valve when the seal is in the decompressed state." At issue between the parties with respect to this term is (1) whether the verb "seal" requires that the opening be fluid tight or just that it be sufficient to prevent leakage and (2) whether this claim term refers only to when the valve is in a decompressed state.

With respect to the first issue, the applicable passage from the Common Specification makes clear that the seal in question is intended to be a fluid tight seal:

> The seal in the decompressed state has a section which fills essentially completely a portion of the cavity adjacent to the opening. The seal section bears against the wall structure near the opening to seal the opening. In the compressed state, the seal section is pushed by the delivery end of the medical implement away from the opening and into the cavity. A fluid tight seal is maintained between the seal section and the wall structure as the seal is moved into the compressed state. The seal section bears against the wall structure as the seal is moved inward into the cavity by the tip of the medical implement ... A fluid tight seal is maintained over repeated opening and closing of the valve ...

Id. At 3:35-57 (emphasis added). The use in two instances of the word "maintained" in describing the fluid tight nature of the seal thus makes clear that the seal described in this claim term is fluid tight at all times.

Although the claim language itself with respect to the second point is somewhat ambiguous, the above quoted passage from the Common Specification also makes clear that this claim term is

not limited to the decompressed state. In particular, the assertion that "the seal section bears against the wall structure as the seal is moved inward into the cavity by the tip of the medical implement" - i.e., when the valve is in the compressed state - makes plain that this claim term is applicable to both the compressed and decompressed states.

The proper construction of "bearing against said wall structure near said opening to seal said opening" is thus "the seal is situated in contact with the wall structure [of the housing] near the opening of the proximal end of the housing to make the opening fluid tight."

IT IS SO ORDERED.

DATED: July 17, 2006

Mariana R. Pfaelzer
United States District Judge

EXHIBIT B

Priority
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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

ICU MEDICAL, INC., a Delaware corporation,

Plaintiff,

v.

ALARIS MEDICAL SYSTEMS, INC., a Delaware corporation,

Defendant.

ALARIS MEDICAL SYSTEMS, INC., a Delaware corporation,

Counterclaim-plaintiff,

v.

ICU MEDICAL, INC., a Delaware corporation,

Counterclaim-defendant.

CASE NO. SA CV 04-689 MRP (VBKx)

JUDGMENT GRANTING DEFENDANT ALARIS MEDICAL SYSTEMS, INC.'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF NONINFRINGEMENT OF "SPIKE" CLAIMS

Having fully considered Defendant Alaris Medical Systems, Inc.'s ("Alaris") Motion For Partial Summary Judgment of Noninfringement of "Spike" Claims, ICU Medical, Inc.'s ("ICU Medical") opposition thereto, Alaris's Reply, the parties' briefs on claim construction, the declarations, exhibits, and memoranda submitted therewith and the relevant authorities cited, and

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the arguments and materials presented at the June 21-22, 2006, Markman and summary judgment hearings,

IT IS ORDERED, ADJUDGED AND DECREED:

1. The SmartSite® Valve and SmartSite Plus® Valve do not infringe, either literally or under the doctrine of equivalents, (1) claims 1, 3-4 and 6-7 of U.S. Patent No. 5,685,866, (2) claims 1 and 2 of U.S. Patent No. 5,873,862, and (3) claims 11, 12 and 16 of U.S. Patent No. 6,572,592;

2. Defendant's motion for partial summary judgment in favor of Alaris and against plaintiff ICU Medical on ICU Medical's third cause of action (alleged infringement of U.S. Patent No. 5,873,862) and fourth cause of action (alleged infringement of U.S. Patent No. 5,685,866) of ICU Medical's amended complaint is granted; and

3. Defendant's motion for partial summary judgment in favor of defendant Alaris and against plaintiff ICU Medical on part of ICU Medical's second cause of action (alleged infringement of U.S. Patent No. 6,572,592) of ICU's amended complaint is granted to the extent that plaintiff's second cause of action relies on ICU Medical's assertion of claims of U.S. Patent No. 6,572,592 that recite a "spike."

Dated: August 24, 2006

Mariana R. Pfaelzer

Hon. Mariana R. Pfaelzer
UNITED STATES DISTRICT JUDGE

EXHIBIT C

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

ICU MEDICAL, INC.,

Plaintiff,

v.

ALARIS MEDICAL SYSTEMS, INC.,

Defendant.

AND RELATED COUNTERCLAIMS

CASE NO. SA CV 04-00689 MRP (VBKx)

JUDGMENT OF INVALIDITY OF PLAINTIFF ICU'S SPIKELESS CLAIMS UNDER 35 U.S.C. § 112, ¶¶ 1 & 2

JUDGMENT

Having considered defendant Alaris Medical Systems, Inc.,'s ("Alaris") Motion for Summary Judgment of Invalidity of "Spike-Less" Claims Under 35 U.S.C. § 112, ICU Medical, Inc.'s ("ICU") Opposition and Alaris' Reply, as well as all submitted supplemental memoranda, declarations and exhibits by both parties, including all relevant authorities cited, and the arguments and materials presented at the hearing,

IT IS HEREBY ORDERED, ADJUDGED AND DECREED:

1. Claims 11-16 of U.S. Patent No. 6,682,509 and claims 17-26, 31-42 and 46 of

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U.S. Patent No. 6,572,592 are INVALID for lack of a sufficient written description, as is required by 35 U.S.C. § 112, first paragraph;

2. Claims 11-16 of U.S. Patent No. 6,682,509 and claims 17-26, 31-42 and 46 of U.S. Patent No. 6,572,592 are INVALID for failing to claim the subject matter that their applicant, Dr. George A. Lopez, regarded as his invention in 1992, as is required by 35 U.S.C. § 112, second paragraph; and

3. Plaintiff ICU's Amended Complaint is hereby DISMISSED WITH PREJUDICE.

IT IS SO ORDERED.

DATED: February 21, 2007

Mariana R. Pfaelzer
Hon. Mariana R. Pfaelzer
United States District Judge

EXHIBIT D

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

ICU MEDICAL, INC.,
a Delaware corporation,

Plaintiff,

v.

ALARIS MEDICAL SYSTEMS, INC.,
a Delaware corporation,

Defendant.

ALARIS MEDICAL SYSTEMS, INC.,
a Delaware corporation,

Counterclaim plaintiff,

v.

ICU MEDICAL, INC.,
a Delaware corporation,

Counterclaim defendant

CASE NO. SA CV 04-0689 MRP (VBKx)

~~[PROPOSED]~~ **FINAL JUDGMENT**

Hon. Mariana R. Pfaelzer

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On August 24, 2006, this Court granted Defendant Alaris Medical Systems, Inc.'s ("Alaris") Motion for Partial Summary Judgment of Noninfringement of "Spike" Claims. On February 21, 2007, this Court further granted Alaris' Motion for Summary Judgment of Invalidity of "Spike-Less" Claims under 35 U.S.C. § 112. As a result, this Court dismissed Plaintiff ICU Medical, Inc.'s ("ICU") Amended Complaint with prejudice, having resolved all counts contained therein.

On April 16, 2007, this Court declared this case "exceptional" pursuant to 35 U.S.C. § 285, granted in part Alaris' Motion for Fees, Costs and Expenses, and granted Alaris' Motion for Sanctions Pursuant to FED. R. CIV. P. 11. On June 28, the Court awarded $4,587,622.74 in attorney's fees and $164,721.19 in non-taxable costs to Alaris pursuant to 35 U.S.C. § 285 and awarded no monetary sanctions under Fed. R. Civ. P. 11. The parties thereafter stipulated to: (1) the entry of additional fees and costs in the amount of $226,000.00 as part of the "fees on fees" portion of the award, and (2) the dismissal without prejudice of all remaining declaratory judgment counterclaims of Alaris. Therefore,

IT IS HEREBY ORDERED that:

(1) In accordance with this Court's August 24, 2006 Order, Alaris is **ADJUDGED** not to have infringed, either literally or under the doctrine of equivalents: (1) claims 1, 3-4 and 6-7 of U.S. Patent No. 5,685,866, (2) claims 1 and 2 of U S. Patent No. 5,873,862, and (3) claims 11, 12 and 16 of U.S. Patent No. 6,572,592,

(2) In accordance with this Court's February 21, 2007 Order, the following claims are **ADJUDGED** to be invalid: (1) claims 11-16 of U.S. Patent No 6,682,509, and (2) claims 17-26, 31-42 and 46 of U.S. Patent No. 6,572,592; and

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(3) Alaris is **AWARDED** attorney's fees and non-taxable costs in the amount of $4,978,343.93, with post-judgment interest to accrue in accordance with the June 28, 2007 award.

Dated: September 21, 2007

Mariana R. Pfaelzer
The Honorable Mariana R. Pfaelzer
United States District Judge

PROOF OF SERVICE

I declare that I am over the age of eighteen (18) years and not a party to this action. My business address is 2049 Century Park East, 34th Floor, Los Angeles, California 90067 and I am employed in the office of a member of the bar of this Court at whose direction this service was made

On **SEPTEMBER 18, 2007**, I served the following document(s) described as:
[PROPOSED] FINAL JUDGMENT

FRANK E. SCHERKENBACH **KAREN I. BOYD** **FISH & RICHARDSON P.C.** **500 ARGUELLO STREET 500** **REDWOOD CITY, CA 94063** **TELEPHONE: (650) 839-5070** **FACSIMILE: (650) 839-5071**	**JENNIFER BUSH** **FISH & RICHARDSON P.C.** **12390 EL CAMINO REAL** **SAN DIEGO, CA 92130** **TELEPHONE: 858-678-5070** **FACSIMILE: 858-678-5099**

☐ **BY MAIL** as follows: I am readily familiar with the firm's practice of collection and processing of correspondence for mailing with the United States Postal Service Under that practice the correspondence was deposited with the United States Postal Service on the same day this declaration was executed in the ordinary course of business. Under that practice the envelope(s) was (were) sealed, and with postage thereon fully prepaid, placed for collection and mailing on this date in the United States Mail at Los Angeles, California addressed as set forth below

☐ **BY PERSONAL SERVICE** as follows: I caused such envelope(s) to be delivered by hand to the addressee(s) at the address set forth below by First Legal Support Messenger Service

☒ **BY FEDERAL EXPRESS** as follows: I placed the document(s) listed above with fees thereon fully prepaid for deposit with Federal Express (next business day delivery), this same day following ordinary business practices to the address(es) set forth below.

☒ **BY FACSIMILE TRANSMISSION** as follows I caused the above-referenced document(s) to be transmitted by facsimile to its intended recipient(s) at the following facsimile number(s) before 5:00 p m.

I declare under penalty of perjury that the foregoing is true and correct and that this declaration was executed on **SEPTEMBER 18, 2007**, at Los Angeles, California.

☒ **FEDERAL:** I declare that I am employed in the office of a member of the bar of this court at whose direction service was made

SHAYNA FISCHER

EXHIBIT E

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MEDEGEN MMS, INC., Plaintiff, v. **ICU MEDICAL, INC.,** Defendant.	Case No. SA CV 06-619 MRP (ANx) **ORDER GRANTING DEFENDANT ICU'S MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT**

I.
INTRODUCTION

In this patent infringement case, Defendant ICU Medical, Inc. ("ICU") seeks summary judgment of noninfringement of Plaintiff Medegen MMS, Inc.'s ("Medegen") only patent-in-suit, U.S. Patent No. 5,730,418 (the "'418 Patent"). The '418 Patent claims an invention for a medical device, specifically a minimum fluid displacement connector that Medegen accuses ICU of infringing with its own medical connector, the CLC2000.

Having read and considered all of the briefs and arguments of the parties, the Court concludes that the CLC2000 does not possess any "plug" or "plug cylindrical distal portion," as claimed by the "displacing means" in asserted means-plus-function claim 28, and dependent claim 42, of the '418 Patent.

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Further, the CLC2000's poppet structure is not an equivalent structure to the "plug" or "plug cylindrical distal portion" of the "displacing means" under 35 U.S.C. § 112, ¶ 6. The CLC2000 therefore does not literally infringe claims 28 and 42 of '418 Patent, and Medegen does not point to any genuine issue of material fact indicating otherwise. The Court therefore GRANTS ICU's Motion for Summary Judgment of Noninfringement.

II.
BACKGROUND

A. Patented Technology

The technology in this case relates to needleless access connectors that interface with an intravenous catheter to deliver medication to a patient from a Luer actuator, such as a syringe. Early designs of these connectors suffered from the problem of unwanted fluid flow into the catheter that occurred each time the connector was used. When the actuator, a Luer tip, is inserted into the connector, the internal volume occupied by the tip of the actuator, however small, causes a positive pressure within the connector that pushes a small amount of fluid out of the connector and into the catheter, termed "antegrade" flow. Similarly, when the Luer is removed, it causes a negative pressure, also roughly equal to the volume of the actuator tip, which draws fluid into the connector through the outlet port, termed "retrograde" flow. Retrograde flow in the connector is undesirable because it may draw blood into catheter or the intravenous tubing that may clot or stagnate. Over time, this stagnated blood can impede fluid flow and present health risks to a patient, requiring either "flushing" of the tube with saline or replacement of the catheter entirely.

Several companies, including Medegen, sought to solve the problem of unwanted retrograde fluid flow by designing connectors that automatically compensate for the volume of the actuator tip upon its insertion and removal from

the connector. Some of these designs aimed to "zero-out" the net fluid flow caused by the insertion of the actuator, while others sought to create a net positive, or antegrade fluid flow when the actuator tip was removed from the connector to facilitate the "flushing" of the connector, tubing and catheter every time the connector was used. The former designs might be called "minimum fluid displacement" connectors and the latter designs "positive fluid displacement" or "self-flushing" connectors, though their differences are not always clear. This is because designing a connector that "zeros-out" or exactly offsets the volume of the actuator tip when inserted and removed is difficult, given the variety of potential actuator shapes and sizes (i.e. Luers of various standardized gauges or volumes) and the actual size variance or manufacturing tolerances that exist even within those standardized actuator sizes. Therefore, a "zero-displacement" or "minimum displacement" connector design may deliberately err on "overcompensating" or generating a net positive fluid flow by default, to avoid the risk of any retrograde flow caused by an unexpectedly large actuator tip. This design precaution carries with it the benefit of flushing the connector as well. In such cases, the design difference between a "minimum/zero displacement" connector and a "self-flushing" connector, if it exists at all, depends on the amount of positive displacement or antegrade flow generated. "Minimum/zero" displacement valves might seek to generate only a small amount of antegrade flow, perhaps enough to cover all expected actuator tip volumes or to minimize any possibility of retrograde flow, while "self-flushing" valves might be designed to guarantee a larger, or unbounded positive fluid displacement in excess of expected actuator volumes.

B. Procedural and Patent Prosecution History

The only patent-in-suit is U.S. Patent No. 5,730,418, or the '418 Patent, which issued on March 24, 1998, based on an application filed on September 30, 1996. ('418 Patent at cover.) It claims an invention for a "Minimum Fluid

Displacement Medical Connector." (*Id.*) Medegen's predecessor, Porex Medical Products, Inc. ("Porex"), originally asserted claims from the '418 Patent against ICU in a lawsuit filed in May 2001. In December 2001, Porex filed a request for reexamination for the '418 Patent and stipulated to a voluntary dismissal of its legal claims, without prejudice, in February 2002, pending the outcome of the reexamination proceeding.

On April 11, 2006, a Reexamination Certificate issued for the '418 Patent ("the '418 RC"), and Porex's successor, Medegen, re-filed its complaint on July 6, 2006. The '418 RC made substantial changes to the '418 Patent. It amended three paragraphs of the specification as well as claims 1-3, 5, 6, 16-27 and 29-32, and it added new claims 33-77, most of which are dedicated to a "self-flushing," as opposed to a "minimum fluid displacement" embodiment.

Originally, Medegen asserted thirteen claims from the '418 Patent against ICU's CLC2000 connector, all of them dedicated to the "self-flushing" embodiment. This consisted of claims 27, 28, 31, 39, 41, 42, 47, 53, 54, 55, 59, 62 and 63, all of which were amended or added by the '418 RC, except claim 28, a means-plus-function claim from the original '418 Patent.

On June 5, 2007, the Court held a *Markman* hearing to construe seven contested terms in the '418 Patent. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). The Court construed six of the seven terms in its June 21, 2007 Claim Construction Order, and held one term did not require construction. After claim construction, Medegen dismissed all of its claims from the case except claims 28 and 42.[1]

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[1] The remaining asserted claims in the '418 Patent, claims 28 and 42, are as follows:

28. A self-flushing connector, comprising:

a valve inlet port adapted for receiving an actuator in an inward direction into the valve inlet port, the actuator having a lumen for introducing fluid through the valve inlet port in the inward direction;

a valve outlet port adapted for transferring fluid in one of a first direction out of the self-flushing connector and a second direction into the self-flushing connector; and

In light of the Court's claim constructions, ICU filed a Motion for Summary Judgment of Noninfringement on June 22, 2007 (the "Motion"). On July 13, 2007, the Court heard oral argument from the parties with respect to ICU's Motion and took it under submission. On July 25, 2007, the Court requested supplemental briefing from Medegen asking it to clarify or amend its contention that ICU's CLC2000 connector infringed the '418 Patent literally and under the doctrine of equivalents. The Court also invited Medegen to suggest what, if any, changes it would make to the Court's construction of the term "displacing means" in claim 28. Responding in a supplemental brief filed August 9, 2007, Medegen did not suggest any modification to the Court's constructions, asking instead only for a "clarification," reiterated its literal infringement contentions and dropped its infringement contentions under the doctrine of equivalents.[2] In light of Medegen's

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displacing means adapted for providing displacements of fluid within the self-flushing connector, the displacing means effecting a relatively small movement of fluid through the valve outlet port in the second direction in response to movement of the actuator in the inward direction, and the displacing means effecting a relatively small movement of fluid through the valve outlet port in the first direction in response to movement of the actuator in an outward direction opposite to the inward direction.

42. The self-flushing connector as recited in claim 28, wherein:

the valve inlet port defines an inlet port axis; and

the valve outlet port defines an outlet port axis that is substantially perpendicular to the valve inlet port axis.

('418 Patent at claims 28 and 42.)

[2] In its supplemental brief, Medegen acknowledged the "confusion introduced by its imprecise use of terminology during its briefing and at the hearing" relating to its assertion of infringement under the "doctrine of equivalents" in its preliminary and final infringement contentions, claim construction materials and summary judgment arguments. (Medegen Opp'n Supp. Br. at 13.) Medegen then unilaterally dropped its infringement contentions under that doctrine, stating that "the doctrine of equivalents is not applicable to a 35 U.S.C. § 112, ¶ 6 analysis because equivalents is already a part of that section." (Medegen Opp'n Supp. Br. at 3.). The Court takes no position on Medegen's decision other than disregarding its previous arguments under the doctrine of equivalents, as Medegen requests. Federal Circuit authority on this issue speaks for itself. *See, e.g.*, *Chiuminatta Concrete Concepts, Inc v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1309-11 (Fed. Cir. 1998) (comparing and applying tests for literal infringement under § 112, ¶ 6 and infringement under doctrine of equivalents, stating, "where the equivalence issue does not involve later-developed technologies, but rather involves technology that predates the invention

abandonment of its infringement contentions under the doctrine of equivalents, the Court invited ICU to file a reply supplemental brief, also asking what, if any, changes it would make to the Court's construction of "displacing means." In its supplemental brief filed on August 20, 2007, ICU, too, accepted the Court's constructions and responded to Medegen's clarified literal infringement arguments. (ICU Mot. Supp. Br. at 1.)

C. Patented Invention

Medegen's patented device, shown below in Figures 1 and 2 of the '418 Patent, essentially consists of: 1) a connector housing (12), comprised of a valve inlet port (21), a valve internal chamber (38), an air chamber (43) and a valve outlet port (36); and 2) an "elastomeric" or "rubberized" plug, otherwise termed a "biased member" (14), that is contained within the connector housing.[3] ('418 Patent at 5:8:45.) The plug, which is biased in the closed position by a shoulder seal (56) and its placement in the connector, and perhaps also with the assistance of a spring (74), has a proximal "portion" (47) that faces the valve inlet port and a distal "portion" (50) that faces the air chamber. (*Id.*) The plug's "portions" perform different functions: the proximal portion (47), or plug head, controls

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itself . . . a finding of non-equivalence for § 112, ¶ 6, purposes should preclude a contrary finding under the doctrine of equivalents."); *Valmont Indus., Inc. v. Reinke Mfg. Co., Inc.*, 983 F.2d 1039, 1042-44 (Fed. Cir. 1993) (also comparing and applying both tests, stating, "A determination of [§] 112 equivalence does not involve the equitable tripartite test of the doctrine of equivalents. As this court has stated, the sole question under [§] 112 involves comparison of the structure in the accused device which performs the claimed function to the structure in the specification. . . . [given that §]112, ¶ 6, limits the broad language of means-plus-function limitations in combination claims to equivalents of the structures, materials, or acts in the specification.").

[3] Though the '418 Patent claims other embodiments as illustrated by other disclosed figures, Medegen states that only the embodiment shown by Figures 1 and 2 reads on the accused ICU CLC2000 connector. The Court, therefore, primarily uses the embodiment found in Figures 1 and 2 to describe the device.

connector activation and fluid flow; the "plug cylindrical distal portion" (70) executes the displacement of fluid; and a raised bump or annular seal at the extreme distal end of the plug, termed a "biased member" (67), is used for "sealingly sliding within the valve distal cylinder" (34). (*See, e.g.*, *id.* at 5:23-65.)

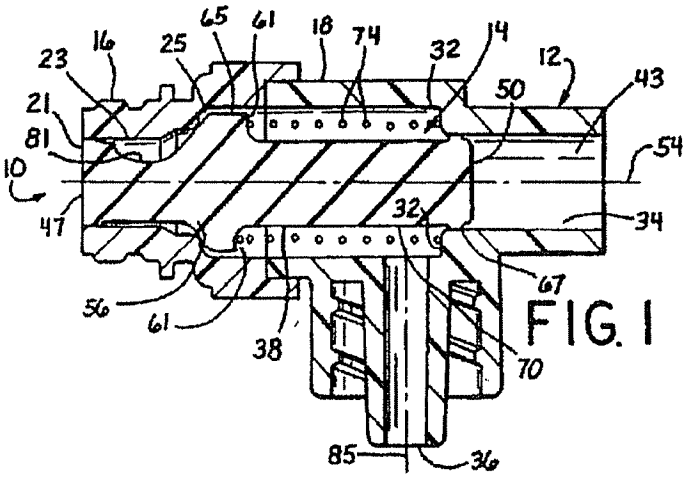
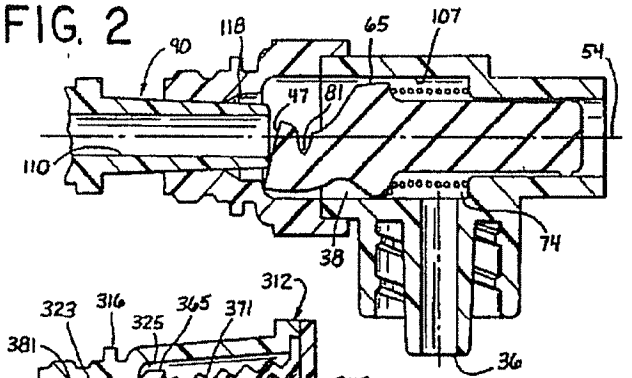


FIG. 1

FIG. 2



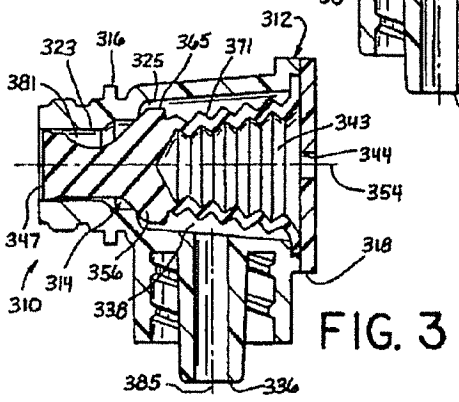


FIG. 3

As shown in Figure 2, the connector is activated when the actuator (90), a Luer or equivalent, is inserted into the connector and pushes on the proximal end of the plug toward its distal end, rotating and collapsing the plug head while pushing the distal portion of the plug towards the air chamber. The movement and

deformation of the proximal portion of the plug opens a fluid pathway within the valve internal chamber, which is always in fluid contact with the valve outlet port, thereby establishing a fluid pathway to the patient. The movement of the cylindrical distal portion of the plug into the air chamber causes a negative fluid displacement, equal to the volume of the plug cylindrical distal portion, within the valve internal chamber that "compensates" for the positive fluid displacement, equal to the volume of the actuator tip, introduced by the insertion of the actuator. (*See, e.g.*, '418 Patent at 2:45-50.) Similarly, when the actuator is removed, the elastomeric plug returns to its original position and shape, perhaps aided with a spring, closing the fluid pathway. Simultaneously, the plug cylindrical distal portion moves out of the air chamber to create a positive fluid displacement that "offsets" or "substantially compensates" the negative fluid displacement caused by the actuator's removal. (*See, e.g.*, *id.* at 2:45-50; 3:1-9; 4:24-29.) The result is that "significant fluid is not displaced during actuation." (*Id.* at 2:37-38.)

It is here that the distinction between "minimum fluid displacement" and "self-flushing" connectors, if any exists, becomes relevant to this case. Medegen's '418 Patent addresses both "minimum fluid displacement" and "self-flushing" embodiments of the connector. Notably, the original '418 Patent focused primarily on the former embodiment while the reexamination significantly fleshed out the latter. For example, the name of the invented device is a "Minimum Fluid Displacement Medical Connector" and much of the specification and claims focuses on a connector that "substantially compensates" or "offsets" the fluid displaced by the insertion of the actuator tip, generating what it terms "zero displacement" within the connector. (*See, e.g.*, '418 Patent at 6:67-7:4 ("In the presently preferred embodiment, the diameter of the plug cylindrical distal portion is configured to be approximately equal (or proportional) to the diameter of the actuator, to thereby yield very close compensating displacements between the two devices."); *see also id.* at 2:45-50; 3:1-9; 4:24-29; 6:62-66.) However, one section

of the original specification and all of the amended claims address "self-flushing" embodiments. (*See, e.g.*, *id.* at 7:4-12 ("If the diameters [of the plug cylindrical distal portion and the actuator] are changed, flushing can be achieved. If the volume of the plug cylindrical distal portion is slightly greater than the volume of the actuator, a small amount of retrograde flow will be created during insertion of the actuator and, subsequently, antegrade (self-flushing) flow will be produced during removal of the actuator. This antegrade flow (self-flushing) produced during removal of the actuator can be considered a desirable feature."); *see also id.* at claims 27, 28 and 53.) Elsewhere in the '418 Patent, asserted claim 31 expressly teaches a "minimum fluid displacement" connector, but also recites that the plug is designed to "*overcompensate* a displacement of fluid in the valve internal chamber that was introduced by insertion of the actuator," thereby also generating a positive fluid displacement. (*See* '418 RC at claim 31, 5:64-67 (emphasis added).) Importantly, the term "overcompensate" replaced the term "offset" in the original claim as a result of the reexamination process. (*See id.*) This dichotomy in the claimed invention pervades the '418 Patent and the '418 RC and is reflected in the Court's claim constructions.

D. Accused Device

The ICU CLC2000 connector was developed in 1996 and became commercially available in 1997. ICU has two patents directed to the CLC2000, U.S. Patent Nos. 6,245,058 and 6,428,520, which issued in June 2001 and August 2002, respectively. Both patents trace priority back to an application filed on December 16, 1996.

According to ICU, its CLC2000 connector is a "positive displacement connector" that provides a constant velocity of fluid that exits the catheter upon removal of the Luer from the connector. This positive displacement prevents unwanted retrograde flow. The positive displacement is achieved by the use of a

"poppet" structure inside the connector that axially shifts away from the connector inlet port upon the insertion of an actuator or Luer. The poppet is made of a rigid polycarbonate and does not pivot or buckle to open a fluid pathway in the connector during use, but instead only moves axially toward the distal end of the connector upon insertion of the Luer. ICU contends that the rigidity of the poppet facilitates high flowrate, linear and consistent positive displacement and complete flushing of the internal space of the connector.

E. Claim Construction

At claim construction, the Court defined the following terms, relevant to ICU's Motion, as indicated:

Claim Term	The Court's Construction
"displacement"	"movement from a previous location"
"self-flushing"	"a net antegrade flow, i.e. fluid flow out of the connector during removal of the actuator"
"displacing means"	• means-plus-function term • function is: "to provide displacements of fluid within the connector" • corresponding structure for the "displacement" function is: "the plug cylindrical distal portion or plug collapsible skirt"
"plug"	"an elastomeric part that either pivots about a reduced diameter portion or buckles, to establish a fluid flow path"
"minimum fluid displacement"	"zero or as close to zero as possible of fluid displaced in or out of the valve outlet port when the actuator is moved into or out of the valve inlet port"
"relatively small movement of fluid"	"movement of a volume of fluid that is more than zero and is approximately equal to the volume of the actuator tip"

III.

LEGAL STANDARD

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). "The evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986); *see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

Literal patent infringement analysis involves two steps: 1) construing the claims; and 2) determining whether the accused product or method infringes the properly construed claims. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1581-82 (Fed. Cir. 1996). "Literal infringement of a [means-plus-function claim under 35 U.S.C. § 112, ¶ 6] requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the structure identified in the written description as corresponding to the recited function." *JVW Enters., Inc. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1333 (Fed. Cir. 2005) (citation and quotation marks omitted). The differences between the relevant structure in the accused device and the structure in the written description must be "insubstantial" to be an equivalent. *Id.* "For example, the structure in the accused device must perform the claimed function in substantially the same way to achieve substantially the same result as the structure in the written description." *Id.*

IV.

ANALYSIS

Only claims 28 and 42 of the '418 Patent remain in this case.[4] Claim 28 teaches a "displacing means adapted for providing displacement of fluid within the self-flushing connector." ('418 Patent at claim 28.) The parties agree that claim 28 is a means-plus-function claim under 35 U.S.C. § 112, ¶ 6. Claim 42 depends from claim 28, and only adds a limitation that the axes of the valve inlet port and valve outlet port are "substantially perpendicular" in Medegen's asserted embodiment of the connector. (*Id.* at claim 42.)

The Court finds that ICU's CLC2000 connector does not literally infringe the '418 Patent, because the CLC2000 does not possess the necessary structure of a "plug" or a "plug cylindrical distal portion" that defines the means-plus-function element "displacing means" in claim 28. Nor is the poppet structure of the CLC2000 a Section 112, paragraph 6 structural equivalent of the "plug" or "plug cylindrical distal portion" structures by which the "displacing means" carries out the function of displacing fluid "within the connector." ICU is therefore entitled to summary judgment of noninfringement.

A. Construction of Means-Plus-Function Claim 28

At claim construction, the Court construed the term "displacing means" in means-plus-function claim 28 in two steps, by: 1) determining the claimed function; and 2) identifying the corresponding structure in the written description performing that function. *See generally JVW Enters.*, 424 F.3d at 1330. The parties agreed, and the Court accepted, that the function of "displacing means" as laid out in claim 28 was "to provide displacements of fluid within the . . .

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[4] The Court notes that claim 42 depends from claim 28, but it has no independent impact on the ensuing infringement discussion. If an accused device does not infringe an independent claim, it also cannot infringe any of the claims that depend from that independent claim. *Wahpeton Canvas Co., Inc. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989).

connector." ('418 Patent at 12:17-26.) However, the parties disagreed on the corresponding structure for the "displacement" function of this definition. The Court ultimately settled on "the plug cylindrical distal portion or plug collapsible skirt," which were the only corresponding structures identified by the claim language and specification as being necessary for the fluid "displacement" function. *See Northrop Grumman Corp. v. Intel Corp.*, 325 F.3d 1346, 1352 (Fed. Cir. 2003) (emphasizing that the corresponding structure in a means-plus-function claim must clearly be linked by the specification or prosecution history to the function recited in the claim). The Court later asked Medegen and ICU for any suggested changes to the construction of "displacing means" in their supplemental briefings, but both Medegen and ICU stated that the Court's construction was correct as it was.

However correct, the Court's construction of "displacing means" requires further elaboration. The function of the "displacing means," verbatim from claim 28 is "providing displacements of fluid within the self-flushing connector." ('418 Patent at claim 28.) The "displacing means" term thus has two limitations: 1) it performs a "displacement" function; and 2) it performs this "displacement" function only "within the connector." In their respective summary judgment arguments, both parties assume that the Court's current construction addresses only the "displacement" function and its corresponding structure, the "plug cylindrical distal portion," but they ignore the rest of the function's text, which contains the explicit requirement that this function be performed "within the connector."[5]

The complete definition of "displacing means" and its functional requirement that the fluid displacement function occur "within the connector" necessitates references to connector structures besides just the "plug cylindrical

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[5] This apparent disconnect between the parties' summary judgment arguments the full meaning of the "displacing means" term in claim 28 prompted the Court's invitation to both parties to provide supplemental briefing on the construction of "displacing means" in the same order that asked Medegen to clarify its infringement contentions.

distal portion." Absent this requirement and these other structures, a "displacing means" that executes fluid displacement via a "plug cylindrical distal portion" in free space makes little sense and would not constitute the actual invention. A closer review of claim 28 in the context of the '418 Patent proves this point. Claim 28 is for a "self-flushing, connector comprising:" 1) a valve inlet port; 2) a valve outlet port; and 3) a "displacing means." It lacks citations to, or descriptions of, other structures or elements "comprising" the other "self-flushing connector" claims of '418 Patent, such as the "air chamber," "valve internal chamber," and, most importantly, the "plug," including both its proximal and distal portions. (*See, e.g.*, '418 Patent at claims 27, 31, 39, 41, 47, 53, 54 59, 62 at 63; *compare id.* at claim 27 *with id.* at claim 28.) Medegen has dismissed all such substantive claims reciting these other structures from this case, particularly claim 27. However, the consistent use of the term "comprising" in these parallel claims and claim 28 indicates that, while they are open-ended, permitting the importation of additional elements, the embodiment of the "self-flushing connector" that Medegen asserts in this case must, at minimum, include these elements or structures.[6]

Accordingly, means-plus-function claim 28 has a discernable scope and claims the actual invention only if it claims a "self-flushing connector" comprising these structures, which must have adequate references in the specification as comprising the "connector." Claim 28 ensures that this is the case by requiring

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[6] *See Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1371 (Fed. Cir. 2005) ("The word 'comprising' transitioning from the preamble to the body signals that the entire claim is presumptively open-ended.") (citations omitted); *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1348 (Fed. Cir. 2001) ("[T]he transition 'comprising' creates a presumption that the recited elements are only a part of the device, that the claim does not exclude additional, unrecited elements.") (citation omitted); *see also* Robert C. Faber, *Landis on Mechanics of Patent Claim Drafting* App. D-5 (5th ed. 2007) (using "comprising" as a transition between the preamble and body of a claim means, "including the following elements [following the word "comprising"], but not excluding others. A claim or clause using [comprising] is said to be open-ended. Thus, 'a composition comprising . . . A, B and C' *requires* the presence of A, B, and C, but does not exclude other components.") (emphasis in original).

that the "displacing means" provide for fluid displacements "within the connector," which the specification describes as including these structures in the asserted embodiment. Alternatively, a "displacing means" with only a "plug cylindrical distal portion," a valve inlet port and a valve outlet port is clearly not a self-flushing connector. Without the whole "plug," including the proximal "portion," the "displacing means" lacks the ability to actuate or control fluid flow "within the connector." Also, without the other structures such as the "air chamber" and "valve internal chamber," fluid displacement could also not occur "within the connector," and neither claim 28 nor the "displacing means" term would adequately claim the invention.

Medegen's argued interpretation of "displacing means" and claim 28 neglects the functional requirement that fluid displacements occur "within the connector," turning claim 28 into a "black box" with few, if any, discernable limitations. In effect, Medegen asserts infringement of the whole "self-flushing connector" invention by citing to fewer elements or structures, or even "portions" of structures, than would otherwise be necessary to claim a complete "self-flushing connector" in claim 28. For example, Medegen claims that the CLC2000 infringes the "displacing means" term of claim 28 because the CLC2000's rigid poppet is a structural "equivalent" to a *portion* of the "plug" in the '418 Patent, specifically the "plug cylindrical distal portion." In other words, irrespective of other structural differences between the connectors, the whole ICU CLC2000 connector infringes the '418 Patent because a *portion* of a single structure within the connector (the poppet) has an outward shape and fluid displacement function that is similar to a *portion* (the "plug cylindrical distal portion") of a single structure (the "plug") recited by the '418 Patent that is composed of different material (elastomeric) and performs other functions ("fluid flow control" and "sealing") in substantially different ways.

An infringement analysis with so narrow a focus turns the structural

"equivalents" analysis under Section 112, paragraph 6, and the related the "all elements" rule under the doctrine of equivalents, on its head. *See Chiuminatta Concrete*, 145 F.3d at 1310 (relating tests for equivalents under § 112, ¶ 6 and the doctrine of equivalents); *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Group, Inc.*, 262 F.3d 1258, 1279 (Fed. Cir. 2001) ("under the 'all elements rule,' there can be no infringement under the doctrine of equivalents if even one element of a claim or its equivalent is not present in the accused device."). It would require that the Court find a device infringes a patented invention because the two have common characteristics when viewing a *portion* of a single element or structure – and no others – in the narrowest, most myopic manner possible. Claim 28 benefits from the convenience of broad means-plus-function claim language under Section 112, paragraph 6, but may do so only by reciting to specific structures in the specification that accomplish the claimed function. *See Med. Instrumentation and Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1211 (Fed. Cir. 2003) (citation omitted) ("The duty of a patentee to clearly link or associate structure with the claimed function is the quid pro quo for allowing the patentee to express the claim in terms of function under section 112, paragraph 6.") The corresponding structure requirement prevents the patentee from "attempting to claim in functional terms unbounded by any reference to structure in the specification." *Id.* However, under Medegen's analysis, any connector that has an internal structure with a cylindrical distal shape that performs a displacement function by axial movement or compression of a "portion" of that structure infringes the '418 Patent, irrespective of other important characteristics, functions or limitations of the structure or element as a whole that are disclosed by the specification. This would violate Section 112, paragraph 6's requirements for means-plus-function claims and would also appear to vitiate several limitations in related claims of the '418 patent, particularly the required "elastomeric" limitation for the "plug" structure, discussed in the next section. *See Warner-Jenkinson Co. v. Hilton Davis Chem.*

Co., 520 U.S. 17, 29 (1997) ("It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety.").

Furthermore, such a broad interpretation of "displacing means" and claim 28 would run afoul of prior art that Medegen has already argued, before the PTO, is not encompassed by the invention claimed by the '418 patent. (*See* '418 Patent Prosecution History at MMS000052, MMS000427 (PTO rejecting all claims as being anticipated by prior art teaching connectors with a displacement function achieved by the axial movement of an internal, cylindrical structure, particularly *Paradis* (U.S. Patent No. 5,509,433), *Ross et al.* (U.S. Patent No. 5,569,235) and *Raines* (U.S. Patent No. 5,147,333)).) Medegen distinguished its invention from this prior art by citing to the very structures it would now avoid including in the "displacing means" term in claim 28, such as the "valve internal chamber," "air chamber" and the "plug." (*See* '418 Patent Prosecution History at MMS000427-31 (distinguishing *Paradis* because it did not disclose an "air chamber," an "internal chamber" and a "plug"; *Ross et al.* because it did not disclose an "air chamber" and a buckling "plug"; and *Raines* because it did not disclose a "plug" or "valve inlet" and "valve outlet" ports in fluid communication with the "valve internal chamber" at all times).) The prosecution history affirms that the coverage of the '418 Patent generally, and claim 28, specifically, in this crowded field is not nearly as broad Medegen's current infringement contentions propound.

Because claim 28 only recites a "displacing means" in a means-plus-function format, this term must serve as a proxy for any "missing" structures, such as the whole "plug," the "air chamber" and the "valve internal chamber," that would be necessary to execute fluid displacements "within the connector" in a manner that claims an actual invention. To its credit, Medegen's original proposed construction for the "displacing means" included these other structures as corresponding structures, but it claimed these functions were necessary for the

"displacement" function, which is inaccurate. These other structures (which, it should be noted, together comprise essentially the entire device) only facilitate or complement the "displacing" function; the only structure the specification and claims expressly associate with performing the "displacement" function, specifically, is the "plug cylindrical distal portion." *See Asyst Techs., Inc. v. Empak, Inc.*, 268 F.3d 1364, 1370-71 (Fed. Cir. 2001) (holding additional structures that do not perform the claimed function are not properly included in a means-plus-function construction). Instead, these other structures perform complementary "fluid flow control" and "sealing" functions that are critical to accomplishing the fluid displacements "within the connector." The Court therefore considers these structures, particularly the entire elastomeric "plug," in the ensuing infringement analysis.

B. Literal Infringement Analysis

ICU argues for summary judgment of noninfringement, because the CLC2000 poppet cannot literally infringe claim 28, since it does not have a "displacing means" or any structural equivalent to the "plug cylindrical distal portion" under Section 112, paragraph 6. ICU maintains that the "plug cylindrical distal portion" is only a portion of the "plug," not a separate piece or part. It therefore must be made of the same elastomeric material that comprises the proximal portion of the plug, which bends and twists upon connector activation to open and close fluid flow, and the annular bump or seal at the distal end, which seals one valve chamber from another. ICU's poppet, which performs the displacing function in the CLC2000, is rigid and is not an equivalent structure since it is composed of substantially different material and accomplishes the "displacement" function in a substantially different way.

Having dropped its infringement contentions under the doctrine of equivalents, Medegen contends that the CLC2000 poppet literally infringes the

'418 Patent and is an equivalent structure to the "plug cylindrical distal portion" under Section 112, paragraph 6. Medegen argues that the CLC2000 poppet performs the same displacement function in a manner similar to the "plug cylindrical distal portion" by moving axially between a chamber containing fluid and one containing air. For the purpose of evaluating literal infringement by an equivalent structure, Medegen urges that any difference between the CLC2000 poppet and the "plug cylindrical distal portion" that is due to differences in their composition – rigid polycarbonate versus elastomeric material – is insubstantial.

As explained above, both parties presume an incomplete definition of the "displacing means" term in making their infringement arguments. Focusing only on the "displacement" function and the corresponding "plug cylindrical distal portion" structure, Medegen's structural "equivalent" argument gives claim 28 too broad a scope and presumes too few limitations. For example, despite the Court's construction defining the "plug" as being elastomeric, Medegen asserts that the "plug cylindrical distal portion" is not necessarily elastomeric, since the elastomeric characteristic of the plug only relates to the proximal portion, whose function is not displacements, but controlling fluid flow by opening and closing the connector. Medegen also points to the raised elastomeric ridge at the extreme distal end of the plug cylindrical distal portion which "sealingly slides" and separates the air chamber from the valve internal chamber, saying it is the structural equivalent of an elastomeric "O" ring that sits at the end of the CLC2000 poppet.

Medegen's argument requires an insupportable parsing of the "plug" into separate parts that may be composed of different materials (i.e. a rigid distal portion with an elastomeric proximal portion). Neither the specification nor the claims disclose a plug composed of separate or distinct "pieces" or "parts," but only discrete "portions" of a single "part" that are devoted to different functions. (*See* '418 Patent at Figs. 1-4, 6-9.) The functions attributed to the various parts of

the plug include: 1) "fluid flow control," using the elastomeric plug proximal portion or plug head; 2) "sealing" off different chambers of the connector, using an elastomeric raised ridge, ill-defined as a "plug biased member," which functions as an annular seal at the extreme distal end of the plug cylindrical portion; and 3) "displacing" fluid, which relies on the volume and shape of the plug cylindrical distal portion as it moves between valve chambers. The specification indicates that the "plug" was designed as one elastomeric piece that could perform all of these functions simultaneously in an advantageously innovative and simple way that was arguably distinct from the prior art. (*See, e.g.*, '418 Patent at 5:46-65, 6:7-30, 6:17-65; '418 RC at 1:28-47; '418 Patent Prosecution History at MMS000427-31 (distinguishing *Paradis, Ross et al.* and *Raines* because they did not disclose a "plug" as described in the '418 Patent).)

Thus, in describing the corresponding structure of the "displacement" function of the "displacing means," the Court's inclusion of the word "plug" in describing the corresponding structure of the "displacement" function of "displacing means" as the "*plug* cylindrical distal *portion*" merely reflects what the written description explicitly states – the entire plug is elastomeric, including the plug cylindrical distal "portion." (*See, e.g.*, '418 Patent col. 5 ll. 10, 24, 27, 30-33, 35, 38, 46, 59; col. 6 ll. 17-18; col. 8 ll. 13, 18, 20-21, 24, 32, 36, 45.) The Court construed the "plug" as being a single, elastomeric part consistent with the preferred embodiment in the '418 Patent, specifically, because that embodiment was the only one the Patent described. *See Unique Concepts v. Brown*, 939 F.2d 1558, 1562 (Fed. Cir. 1991) (when a patentee throughout the specification and prosecution history describes the invention as having a certain structural or functional limitation, the patentee cannot point to an isolated suggestion in the specification to eliminate that limitation). Nowhere is the "plug cylindrical distal portion" referred to as a separate structure from the rest of the plug or as being made of a different kind of material.

It follows that Medegen's infringement contention comparing only the "plug cylindrical distal portion" to the entire CLC2000 poppet as an equivalent structure ignores the other structures that are necessary to accomplishing fluid displacement "within the connector." This includes, at minimum, the whole elastomeric plug, including its proximal portion, which uses the buckling plug head to control fluid flow and an annular raised ridge at its distal end to seal the connector's chambers. The proper comparison is thus between the whole poppet structure in the CLC2000 and the whole "plug" structure described in the '418 Patent, as claimed by the "displacing means" in claim 28.

This more apt comparison shows that claim 28 does not literally read on the CLC2000. The Court construed the "plug" in the '418 Patent as: "an elastomeric part that either pivots about a reduced diameter portion or buckles, to establish a fluid flow path." In contrast, ICU's CLC2000 and its comparable poppet structure is made of a rigid polycarbonate that does not buckle or pivot in order to establish a fluid flow path. ICU's device therefore lacks any "plug," as defined by the '418 Patent, as well as any structure with the "elastomeric," "buckling" and "pivoting" limitations found in the "plug." The CLC2000 therefore cannot literally infringe the "displacing means" of claim 28. *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1321 (Fed. Cir. 2006) (no infringement where a claim limitation is missing from the accused device).

The poppet is also not a structural equivalent to the "plug" or "plug cylindrical distal portion" of the "displacing means" term under Section 112, paragraph 6. For starters, Medegen has provided no evidence that the rigid poppet and the elastomeric plug or plug cylindrical distal portion are interchangeable, nor have they shown that a person reasonably skilled in the art would have known of this interchangeability. *See Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1309 (Fed. Cir. 1998) (finding that whether a person reasonably skilled in the art knew of the interchangeability of one structure that

was disclosed in the patent with another that was not is an important factor in whether two structures are equivalent under Section 112, paragraph 6).

In fact, while the two structures both accomplish "fluid flow control" and "sealing" functions in order to execute their respective fluid "displacement" functions "within the connector," they do so in substantially different ways. This is primarily due to the fact that the two structures are composed of different materials with fundamentally different physical characteristics that directly affect how each executes fluid displacements "within the connector." The poppet in the ICU CLC2000 connector is made of a rigid polycarbonate, while the "plug" in the '418 Patent, including "cylindrical distal portion" is made of a flexible, elastomeric material. The flexible, elastomeric composition of the "plug" allows it to pivot and buckle during connector use and then return to its original shape, thereby opening and closing the fluid pathway while controlling fluid displacements "within the connector." In contrast, the rigid polycarbonate poppet in the CLC2000 was designed to achieve: 1) a high fluid flow rate; 2) linear, constant positive fluid displacement; 3) complete flushing of the internal connector space. It works by moving axially into the connector as a single, non-deforming piece to open and close a fluid pathway circumferentially around the depressed, but unchanged poppet head. The composition of the structures and the way the two structures achieve fluid "displacement" "within the connector" is substantially different.

These differences eclipse any apparent similarities the two structures may share in the axial movement and cylindrical shape of their "displacing" distal sections, which appear to be features found even in the prior art. (*See* '418 Patent Prosecution History at MMS000052, MMS000427 (rejecting all claims as being anticipated by prior art teaching connectors with a displacement function achieved by the axial movement of an internal, cylindrical structure, particularly *Paradis* (U.S. Patent No. 5,509,433), *Ross et al.* (U.S. Patent No. 5,569,235) and *Raines* (U.S. Patent No. 5,147,333)).) While the two structures here also share an

elastomeric "sealing" element or structure at their distal end, this is a fairly inconsequential feature of both inventions. Still, notable differences exist even in those structures, as the CLC2000 uses a separate, torus-shaped, elastomeric "O" ring part that is wrapped around the distal end of the poppet, while Medegen's "plug," which comprises a single elastomeric piece, uses a raised bump of the same elastomeric material at its distal end.

In total, no reasonable jury could find that the two structures execute the fluid "displacing" function "within the connector" in substantially similar ways. In a crowded field such as this one, the compositional differences in the two fluid displacing structures, the poppet and the "plug," are important and substantial given that neither the '418 Patent, nor claim 28 or its "displacing means" teaches a rigid plug or a plug with any rigid, non-elastomeric portion. The poppet and "plug" or "plug cylindrical distal portion" are not interchangeable because of these differences in composition and, ultimately, their way of accomplishing the "displacement" function "within the connector." Otherwise, Medegen raises no genuine issue as to any material fact demonstrating that the CLC2000 connector infringes Medegen's '418 Patent. ICU is entitled to a judgment of noninfringement as a matter of law.

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CONCLUSION

The Court concludes that because the poppet structure in ICU's CLC2000 connector is not a "displacing means," as used in asserted claim 28, and because the poppet is not an equivalent structure to the "plug" or "plug cylindrical distal portion" under Section 112, paragraph 6, ICU's connector does not literally infringe claims 28 and 42 of Medegen's '418 Patent. The Court therefore GRANTS ICU's Motion for Summary Judgment of Noninfringement.

IT IS SO ORDERED.

DATED: September 14, 2007

Hon. Mariana R. Pfaelzer
United States District Judge

EXHIBIT F

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

ICU MEDICAL, INC.,

Plaintiff,

v.

B. BRAUN MEDICAL, INC.,

Defendant.
_____/

No. C 01-03202 CRB

CLAIM CONSTRUCTION ORDER

This suit involves the alleged infringement of United States Patent No. 5,928,204 (the "'204 Patent"). This patent relates to technology for administering or withdrawing fluids from medical patients by means of valves that do not require needles or numerous mechanical parts. Specifically, the '204 Patent discloses a "closed system, needleless valve device" that includes, *inter alia*, a resilient silicone seal that facilitates the smooth flow of fluids from a blunt cannula through a catheter to the patient. Now before the Court is the task of construing certain claim terms over which the parties remain in dispute.

CLAIM CONSTRUCTION

A. Legal Standards for Claim Construction

Patent infringement analysis involves two steps. The first step is to construe the asserted claims, and the second step is to determine whether the accused method or product infringes any of the claims as properly construed. See Markman v. Westview Instruments,

Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). The first step, construction of the patent claims, is a matter of law and thus the responsibility of the court. See id. at 979.

Extrinsic evidence, such as expert and inventor testimony, dictionary definitions, and learned treatises, may be admitted in the court's discretion "for background and education on the technology implicated by the presented claim construction issues." Key Pharm. v. Hercon Labs. Corp., 161 F.3d 709, 716 (Fed. Cir. 1998). However, "[i]n interpreting an asserted claim, the court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996).

In examining the intrinsic evidence, the court should first look to the words of the claims themselves to define the scope of the patented invention. See id. Words in a claim "are generally given their ordinary and customary meaning." Id.

Second, the court should review the patent specification "to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." Id. "The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Id. The Federal Circuit teaches that "the specification is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term." Id. Drawings included in the patent application have the same effect on claim language as other portions of the specifications. See Autogiro Co. of America v. United States, 384 F.2d 391, 398 (Ct. Cl. 1967).

The third type of intrinsic evidence that the Court may consider is the prosecution history of the patent, if it is in evidence. See Vitronics, 90 F.3d at 1582. The prosecution history contains the entire record of the prosecution of the patent claim before the patent office, including any representations about the scope of the claim or the meaning of certain terms made by the applicant.

Ordinarily, the intrinsic evidence alone will resolve any ambiguity in a disputed term. By relying first on the claim language, the specification, and the prosecution history, a court can protect a patentee's rights while at the same time enabling the public to rely on the public record of the patentee's claim. "In other words, competitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention and, thus, design around the claimed invention." Vitronics, 90 F.3d at 1583 (citing Markman, 52 F.3d at 978-79). For these reasons, "[o]nly if

there [is] still some genuine ambiguity in the claims, after consideration of all available intrinsic evidence, should the trial court[] resort[] to extrinsic evidence." Id. at 1584; see Key Pharm., 161 F.3d at 716 (noting that extrinsic evidence is appropriate if the intrinsic evidence "does not answer the question").

B. Does Claim 1 Require That The Seal Have Arcuate Segments In Its Uncompressed State?

The central dispute between the parties is whether Claim 1 refers only to a seal in its ordinary uncompressed state or refers as well to a seal in its compressed state. Stated differently, the issue is whether Claim 1 reads on a seal that is arcuate only when compressed. Because the accused device is arcuate when compressed but flat-walled when decompressed, this determination is highly significant to the outcome of the litigation.

Neither the claim language nor the specification is helpful in this regard. Contrary to defendant's assertions, the ordinary meaning of the word "seal" conveys nothing about relative states of compression. While addition of the modifier "resilient" may connote a particular variety of seal that is subject to compression, by itself it does not indicate whether the rest of the claim pertains to the seal in its compressed state, its uncompressed state, or both. The specification describes the seal in both compressed and uncompressed states.

The parties offer conflicting interpretations of the prosecution history. In particular, they differ with respect to the implications of the examiner's initial determination that the claim that later became Claim 1[1] was anticipated by the Armao patent (the "'380 Patent," or "Armao"). That patent, which was directed toward shielded hypodermic needles, disclosed at least one exemplary embodiment having arcuate segments only in the compressed state, see '380 Patent, Figs. 4-5, and another embodiment having arcuate segments when compressed and arcuate segments housed in a flat-walled sheath when uncompressed. See id. Figs. 6-7.

Plaintiff argues that the examiner's rejection of Claim 1 signified his determination that the claim was anticipated by--and hence read on--seals having arcuate segments only when compressed. Although plaintiff subsequently distinguished Claim 1 from Armao, it did so by not by amending this aspect of the claim, but rather by adding a limitation directed toward the relative diameters of the various seal segments.

[1]Prior to issuance, Claim 1 of the '204 Patent was claim 67 of the patent application. For ease of reference, this Order will refer to the claim as Claim 1 both before and after it issued.

Plaintiff therefore argues that the claim as it emerged from patent prosecution covered seals that were arcuate only when compressed as well as seals that were arcuate in both their compressed and uncompressed states.

Defendant objects to this characterization of the prosecution history. According to defendant, the examiner rejected Claim 1 only in light of Figure 6 of the Armao patent–that is, the figure depicting arcuate segments in the seal's uncompressed state. The examiner did *not* find, argues defendant, that Claim 1 was anticipated by the embodiment of Armao having arcuate segments only when compressed. Moreover, the fact that the examiner did not reject the amended Claim 1 as anticipated by other prior art references having arcuate segments only when compressed demonstrates, according to defendant, that the claim is limited to a seal that is arcuate in its uncompressed state.

Examination of the file wrapper lends no support to defendant's characterization of the patent examiner's thought processes. The Court must presume that the examiner gave the term "seal" its broadest reasonable interpretation. See Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1347 (Fed. Cir. 2001). While it is true that the examiner directed the applicant's attention to Figure 6 of Armao in connection with its statement that Claim 1 was "rejected . . . as being clearly anticipated by Armao," see Ex. P to Taclas Decl., at ICU-BB 00686, the full extent of the examiner's commentary to this effect was the notation "Note figure 6." This falls short of establishing that the examiner believed that the claim was anticipated *only* by seals having arcuate segments in both compressed and uncompressed states.

Defendant's argument premised on the fact that the examiner did not reject Claim 1 as anticipated by other prior art references is also unconvincing. The file wrapper is understandably silent as to what the examiner did *not* do, and the universe of possible reasons for the examiner's allowance of Claim 1 over the prior art includes many having nothing to do with whether a seal is arcuate in a particular state. See Verdegall Bros. v. Union Oil Co., 814 F.2d 628, 631 (Fed. Cir. 1987) (pending claims should be allowed unless "each and every element of the claimed invention [is] disclosed" by the prior art). As such, it is impossible to conclude that the claim's allowance signifies the examiner's determination that the claim does not read on seals that are arcuate only when compressed. See Inverness Med. Switzerland v. Warner Lambert Co., 309 F.3d 1373, 1382 (Fed. Cir. 2002) ("It is inappropriate to limit a broad definition of a claim term based on prosecution history that is itself ambiguous.").

For these reasons, the Court declines to construe this claim as limited to seals having arcuate segments in their uncompressed state.

C. Other Disputed Terms

1. "A seal for use in selectively opening and closing a fluid pathway through a medical connector"

Plaintiff argues that this phrase, which appears in Claim 1, refers simply to a seal that is deployed in the context of opening and closing a fluid pathway through a medical connector. Defendant argues that any device that opens and closes a fluid pathway functions as a valve, and therefore proposes that "seal" be construed to mean "a seal that must be capable of the additional function of acting as a valve to selectively open and close a fluid pathway through a medical connector."

Whether or not defendant is correct that a device that opens and closes a pathway is necessarily a valve, defendant's proposed construction completely ignores the words "use in." That is, whereas the claim discloses "a seal *for use in* . . . opening and closing a fluid pathway," defendant's construction reads the claim to disclose "a seal *for* opening and closing a fluid pathway." As defendant would construe the claim, it would suggest that the seal itself is the device that opens and closes the pathway. However, the abstract and specification plainly teach that the seal is to be incorporated into a valve, not that it is to function as a valve on its own. See, e.g., Abstract ("The valve also *includes* a plastic, resilient silicone seal . . . ."); Col. 2:41-42 ("A two-way valve is employed *utilizing* a reusable seal . . . ."). The specification further reveals that it is only when the seal interacts with other elements of the valve assembly that fluid is able to flow through the pathway. See Col. 8:66-9:15.

As such, there is no reason to insert defendant's proposed limitation into Claim 1. The Court will construe this term in the manner proposed by plaintiff.

2. "resilient seal element"

The parties also dispute the meaning of the term "resilient seal element" in Claim 1. According to plaintiff, the term refers to "a sealing portion capable of returning to its original position after being bent, compressed or stretched." Defendant contends that the seal must be "prepared from a resilient material that is flexible, inert, and impermeable to fluid." The question is thus whether the word "resilient" refers to the behavior of the seal or its composition.

Defendant's proposed construction strains the term's ordinary meaning. Unlike a term such as "rubber seal" or "silicone seal," the term "resilient seal," absent more, does not connote a seal element that is made of a particular material. As such, defendant's construction seeks to add a limitation that is neither inherent in the claim language nor suggested by the specification or prosecution history. Indeed, the specification reveals that the invention is not limited to seals of a particular composition. See Col. 3:63-63 ("*In one embodiment*, . . . the seal is made of a material having a hardness of from 30 to 70 Shore units such as, *for example*, a silicone polymer.") (emphasis added). "[C]laim terms take on their ordinary and accustomed meanings unless the patentee demonstrated an intent to deviate . . . by redefining the term . . . in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2002). Here, there is no indication that plaintiff meant to disclaim seals of any particular composition.

Defendant also seeks to read into the term a requirement that the seal element "act[] as a pierceable or pre-slit valve to selectively open and close a fluid pathway." There is no basis for incorporating this limitation into the term. Since the proper construction of "seal" does not include defendant's proposed limitation that the seal itself must open and close a fluid pathway, defendant's attempt to read a similar limitation into the phrase "resilient seal element" must necessarily fail as well. Accordingly, this term will be construed in the manner proposed by plaintiff.

3. "Top end" and "bottom end"

The next dispute involves the proper construction of the terms "top end" and "bottom end" in the phrase "a resilient seal element having a wall having a top end and a bottom end." Defendant argues that the "top end" is the end that consists of an arcuate segment having a smaller maximum diameter than the arcuate segment at the "bottom end," and that the "bottom end" is the end opposite the "top end." By contrast, plaintiff seeks to construe "top" and "bottom" by reference to the point in the system where the fluid pathway is opened and closed.

Although the end of the seal containing the narrower arcuate segment may, in practice, be the end nearest to where the fluid pathway is opened and closed, the claim language does not require such a result. Claim 1 discloses "a wall having a top end and a bottom end, said wall including . . . at least one segment proximate to said bottom end having a larger maximum diameter than a second segment nearer to said top

end of said element." As written, therefore, the claim identifies the "bottom end" as the end proximate to the segment with the larger maximum diameter, and the "top end" as the end proximate to the segment with the shorter maximum diameter. Nothing about this language requires that the seal be oriented in any particular direction vis-a-vis the point at which the fluid pathway is opened.

Plaintiff further argues that the specification indicates that the "top end" of the seal is always the end nearest where the fluid pathway is opened and closed. In fact, however, the specification reveals only that the "proximal" end of the internal cavity of the valve body is nearest that point, not that the top end of the seal is necessarily near it as well. See Col. 2: 52-54. Given the heavy presumption that a claim term takes on its ordinary meaning, see Teleflex, 299 F.3d at 1327, the Court declines to construe the "top end" of the seal as interchangeable with the "proximal end" of the internal cavity.

Moreover, the prosecution history reveals that the portion of the claim containing the references to the top and bottom ends of the seal wall was added in order to distinguish over Armao's non-tapered seal. As such, the terms "top end" and "bottom end" are more properly defined by reference to the tapering of the seal than in terms of their location vis-a-vis the fluid pathway.

Accordingly, "top end" and "bottom end" will be construed in the manner proposed by defendant.

4. "Maximum diameter"

Finally, the parties disagree as to the meaning of the term "maximum diameter" in the phrase "at least one segment proximate to said bottom end having a larger maximum diameter than a second segment nearer to said top end of said element." Whereas plaintiff contends that the term should be given its ordinary meaning, defendant submits that the proper construction is "the diameter to the outside surface of the outwardly extending portion of each discrete, arcuate segment." Plaintiff objects to defendant's proposed construction because it would allegedly read the word "maximum" out of the term. Defendant objects to plaintiff's proposed construction because it allegedly implies that a particular arcuate segment can have multiple maximum diameters.

In fact, plaintiff does not suggest that any one segment can have multiple maximum diameters; rather, plaintiff's position is that a given segment of a resilient seal may compress to a slightly different diameter each time it is compressed, such that "maximum diameter" refers to the largest diameter that the segment will ever achieve when compressed. In this sense, the claim allows for the possibility that on any

given compression, the seal might not taper perfectly. Meanwhile, defendant's construction does not ignore the word "maximum." Rather, defendant's proposed construction specifies that the measurement should be taken to the outermost portion of a given segment, and defendant explicitly states that "the 'maximum diameter' refers to the largest straight line passing through the center of the . . . 'arcuate segment[].'" Def.'s Br. in Opp., at 33. When the parties' respective positions are properly understood, therefore, they are not inconsistent: Both parties understand the term to refer to the characteristic of the seal whereby the arcuate segments at the bottom end have larger maximum diameters than the segments at the top end.

Accordingly, the term "maximum diameter" will be construed to mean "the longest straight line passing through the center of an arcuate segment."

CONCLUSION

In addition to the construction of disputed terms and phrases supplied above, the Court adopts the agreed construction of the parties as set forth in the "Amended Joint Claim Construction Statement" filed July 3, 2002.

IT IS SO ORDERED.

Dated: November 27, 2002

/s/
CHARLES R. BREYER
UNITED STATES DISTRICT JUDGE

United States District Court
For the Northern District of California

EXHIBIT G

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ICU MEDICAL, INC., Plaintiff, **v.** **B.BRAUN MEDICAL INC.** Defendant.	**Civil Action No. CV 01-3202 CRB/MEJ**

STIPULATED ORDER OF DISMISSAL WITH PREJUDICE

IT IS HEREBY STIPULATED AND AGREED by and among the undersigned pursuant to Federal Rule of Civil Procedure 41(a)(1)(ii) that this action be, and hereby is, dismissed with prejudice, including any and all claims and defenses asserted by the parties including Braun's defenses of inequitable conduct and invalidity, and ICU's claims of infringement. Each of the parties shall bear its own fees, costs, and expenses.

SO ORDERED:

Dated: April 20, 2005

Honorable Charles R. Breyer
United States District Judge

Dated: April 20, 2005

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Attorneys for Plaintiff
RYMED TECHNOLOGIES, INC.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

Case No. SACV07-1199 DOC (ANx)

RYMED TECHNOLOGIES, INC., a Delaware corporation,

Plaintiff,

vs.

ICU MEDICAL, INC., a Delaware corporation,

Defendant.

COMPLAINT FOR INJUNCTIVE RELIEF AND DAMAGES FOR:

1. **DECLARATORY JUDGMENT RE NON-INFRINGEMENT AND INVALIDITY OF PATENTS;**
2. **LANHAM ACT VIOLATIONS;**
3. **FEDERAL TRADEMARK INFRINGEMENT;**
4. **FEDERAL UNFAIR COMPETITION;**
5. **STATE TRADEMARK INFRINGEMENT;**
6. **STATE UNFAIR COMPETITION; AND**
7. **RELATED CLAIMS**

DEMAND FOR JURY TRIAL

Plaintiff RYMED TECHNOLOGIES, INC. ("RyMed") alleges:

JURISDICTION

1. This action arises under violations of federal patent law, the Lanham Act (15 U.S.C. §§ 1051-1127 *et seq.*), California statutory trademark infringement law (Cal. Bus. & Prof. Code Section 14335), California statutory unfair competition law (Cal. Bus. & Prof. Code Sections 17200 and 17500), and California common law doctrines of passing off, unfair competition, intentional interference with contract, intentional interference with prospective business and economic advantages. Accordingly, this Court has subject matter jurisdiction pursuant to 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331, 1338, 1367, and 2201-2202. Jurisdiction over the patent claims and the Lanham Act claims exists pursuant 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331, 1338, and 2201-2202. This Court has jurisdiction over the California state law claims pursuant to 28 U.S.C. §§ 1338 and 1367.

2. Upon information and belief, this Court has personal jurisdiction over Defendant ICU Medical, Inc. ("ICU") because ICU's principal place of business is in this District. As such, ICU has transacted business in this District, contracted to supply goods or services in this District, and has purposefully availed itself of the privileges and benefits of the laws of the State of California. This Court also has jurisdiction over ICU because it has committed violations of federal patent law, the Lanham Act, and California law during the course of its business in this District.

VENUE

3. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) because ICU resides in this District, maintains its principal place of business in this District and may otherwise be found here, is subject to personal jurisdiction in this District, and a substantial part of the events, omissions, and injuries giving arise to RyMed's claims occurred in this District.

PARTIES

4. Plaintiff RyMed is a corporation duly organized and existing under the laws of Delaware, having a principal place of business at 137 Third Avenue North, Franklin, Tennessee.

5. Upon information and belief, Defendant ICU is a corporation duly organized and existing under the laws of Delaware, having a principal place of business at 951 Calle Amanecer, San Clemente, California.

FACTUAL ALLEGATIONS

RyMed's Business

6. RyMed specializes in the design, development, and marketing of innovative safety products in the field of intravenous catheter care management.

7. RyMed is the owner of U.S. Trademark Registration No. 3,168,566, issued on November 7, 2006, for the mark NEUTRAL® for use in association with needleless I.V. connectors and injection ports for use in the aspiration and administration of blood and intravenous fluids. RyMed has used its NEUTRAL® mark since at least December 1, 2005. This registration, duly and legally issued by the United States Patent and Trademark Office, is valid and subsisting. Registration Number 3,168,566 is attached hereto as Exhibit A to this Complaint.

8. Through its extensive use of the NEUTRAL® mark, RyMed also owns common law trademark rights in its NEUTRAL® mark and in association with its commercial products: the InVision-Plus® NEUTRAL® I.V. Connector System.

The InVision-Plus® NEUTRAL® I.V. Connector System

9. RyMed created the InVision-Plus® NEUTRAL® I.V. Connector System, which is designed to prevent blood reflux into a catheter when the InVision-Plus® NEUTRAL® is connected to and disconnected from a syringe and/or I.V. set. This product reduces the possibility of intraluminal thrombotic catheter occlusions, as well as reduces the possibility of intraluminal catheter-related bloodstream infections.

10. The InVision-Plus® NEUTRAL® I.V. Connector System is the first injection port developed in the medical field that demonstrates a zero fluid displacement feature, meaning no reflux of blood into the catheter lumen following connection to, or disconnection from, the injection port. The InVision-Plus® NEUTRAL® product has no negative fluid displacement, meaning that immediately upon connection to the InVision-Plus® NEUTRAL® I.V. Connector, 0.000mL (-0.000mL/+0.002mL) of fluid is displaced, and immediately upon disconnection from the InVision-Plus® NEUTRAL® I.V. Connector, 0.000mL (+/- 0.000mL) of fluid is displaced. The Fluid Displacement Study protocol and test results were developed and reported by an independent testing laboratory (Nelson Laboratories, Inc., Salt Lake City, UT). The data from the Nelson Laboratories study demonstrated that the InVision-Plus® NEUTRAL® I.V. Connector System has no fluid movement refluxing into a tubing lumen equivalent to a 2 Fr catheter with an average distance of 0.00mm.

11. As a consequence of the extensive sales under, and advertising, promotion, and use of the NEUTRAL® mark, RyMed has developed significant recognition in its NEUTRAL® mark. RyMed has acquired and enjoys a valuable reputation and tremendous goodwill under the NEUTRAL® mark.

The InVision-Plus® NEUTRAL® with Modified Boot

12. RyMed has also designed and created a new product, the InVision-Plus® NEUTRAL® with Modified Boot. RyMed has taken concrete steps with the intent to manufacture, sell, and offer to sell in the United States the InVision-Plus® NEUTRAL® with Modified Boot. These steps include:

a. The completion of all engineering design drawings for the new modified boot;

b. The completion of all engineering functional testing on the new modified boot;

c. The completion of all sterilization testing on the new modified boot;

d. The development of a large cavitation production mold of the new modified boot design scheduled for completion in the late fourth quarter of 2007; and

e. The preparation of sales and marketing literature for the new modified boot design;

RyMed expects to offer the InVision-Plus® NEUTRAL® with Modified Boot for sale in the first quarter of 2008.

ICU's Business

13. Upon information and belief, ICU develops and manufactures safety products in the field of intravenous catheter care management.

14. Upon information and belief, prior to RyMed's adoption of the NEUTRAL® mark, ICU marketed and sold its CLAVE® and MicroCLAVE® products, which are both needleless I.V. connectors used in the aspiration and administration of blood and intravenous fluids. Approximately eighteen months after RyMed started using its NEUTRAL® mark, ICU renamed its original MicroCLAVE® I.V. Connector to MicroCLAVE® NEUTRAL I.V. Connector, and continues to market and sell the MicroCLAVE® Connector product under its new tradename. ICU's MicroCLAVE® Neutral Connector product is ostensibly designed to minimize blood reflux into a catheter when a syringe and/or I.V. set is connected to and disconnected from the MicroCLAVE® Neutral Connector.

15. Upon information and belief, ICU markets its MicroCLAVE® Neutral Connector product as having zero fluid displacement or reflux. However, a Fluid Displacement Study by Nelson Laboratories, Inc., Salt Lake City, UT, demonstrated that ICU's MicroCLAVE® Neutral Connector product is not a zero fluid displacement I.V. connector. The study reflected immediately upon disconnection from the MicroCLAVE® Neutral Connector, a volume of 0.028mL of fluid is refluxed. The data from the Nelson Laboratories study further reflects the MicroCLAVE® Neutral Connector product refluxed into a tubing lumen equivalent to a 2 Fr catheter with an

average distance of 47.81mm. For the CLAVE® I.V. Connector, the Nelson Laboratory Study reflected that a volume of 0.022mL of fluid is refluxed immediately upon disconnection. The data from the Nelson Laboratories study further reflects the CLAVE® I.V. Connector product refluxed into a tubing lumen equivalent to a 2 Fr catheter with an average distance of 37.11mm. As such, the MicroCLAVE® Neutral Connector product refluxes more fluid than ICU's CLAVE® I.V. Connector product.

16. ICU fully incorporates RyMed's NEUTRAL® mark in the name of its MicroCLAVE® Neutral Connector product, a product which occupies the same field as RyMed's InVision-Plus® NEUTRAL® I.V. Connector System. As such, consumers are likely to be confused that RyMed is the source or sponsor of ICU's MicroCLAVE® Neutral Connector product or that there is an association between RyMed and ICU. Upon information and belief, ICU markets its MicroCLAVE® Neutral Connector product as having zero fluid displacement.

ICU's False Statements

17. ICU seeks to maintain its market share in the field of intravenous catheter care management. In order to do so, upon information and belief, ICU has disseminated, used, and sponsored materially false and misleading advertising, promotional, "educational," and other materials that discredit and disparage RyMed's products, misrepresent ICU's products, and misrepresent the Food & Drug Administration's ("FDA's") investigation of RyMed and RyMed's voluntary recall of specific lots of its InVision-Plus® NEUTRAL® I.V. Connector System. Upon information and belief, the false and misleading statements ICU has made, used, sponsored, and promoted to RyMed's customers and/or potential customers include:

a. that RyMed's products are unsafe due to coring and particulate matter flowing into the patient's fluid pathway;

b. that with respect to the FDA's investigation of RyMed, RyMed's actions are a serious offense, even though RyMed has completed the voluntary

recall of specific lots of its InVision-Plus® NEUTRAL® I.V. Connector System and the FDA considers the recall completed and terminated;

c. that RyMed has been sued by ICU and RyMed has serious patent infringement problems with ICU's patents;

d. that ICU's MicroCLAVE® Neutral Connector product is a zero fluid displacement product;

e. that ICU's MicroCLAVE® Neutral Connector product is a saline flush only product because of its zero fluid displacement feature;

f. that RyMed's InVision-Plus® NEUTRAL® I.V. Connector System product trials have gone very poorly, the product has coring of the septum, and the product has serious patent infringement problems; and

g. that RyMed's InVision-Plus® NEUTRAL® I.V. Connector System has potential coring problems.

18. Among numerous other reasons, these statements were and continue to be false and misleading because:

a. RyMed's products are safe;

b. The FDA confirmed that RyMed's corrective actions regarding its InVision-Plus® NEUTRAL® I.V. Connector System were appropriate, no further action was required, and the FDA considers the recall completed and terminated;

c. RyMed does not infringe ICU's patents;

d. ICU's MicroCLAVE® Neutral Connector product is not a zero fluid displacement product;

e. ICU's MicroCLAVE® Neutral Connector product has a label claim that states it is a saline flush only product based upon false internal documentation that it has a zero fluid displacement feature; and

f. RyMed's InVision-Plus® NEUTRAL® I.V. Connector System product

trials have not gone poorly, nor does the product have coring of the septum or potential coring problems if used according to directions for use.

19. ICU also distributed misleading product literature designed to suggest the document originated from RyMed. An example of such literature is attached hereto as Exhibit B.

20. ICU intended to deceive and/or mislead RyMed's customers and/or potential customers, and did deceive and/or mislead them.

21. Upon information and belief, ICU was aware of a distribution agreement between RyMed and Co-Medical, Inc. ("Co-Medical").

22. Upon information and belief, ICU met with Co-Medical in early August 2006 and pressured Co-Medical to either discontinue its relationship with RyMed or risk losing ICU's business.

23. Co-Medical contacted RyMed after the ICU meeting and terminated its distribution agreement with RyMed in violation of the terms of that agreement.

The Patents-In-Suit

24. Upon information and belief, ICU is the owner of the entire right, title, and interest in and to United States Patent No. 5,685,866 ("the '866 patent") entitled "Medical Valve and Method of Use." A true and correct copy of the '866 patent is attached hereto as Exhibit C to this Complaint.

25. Upon information and belief, ICU is the owner of the entire right, title, and interest in and to United States Patent No. 5,873,862 ("the '862 patent") entitled "Medical Valve and Method of Use." A true and correct copy of the '862 patent is attached hereto as Exhibit D to this Complaint.

26. Upon information and belief, ICU is the owner of the entire right, title, and interest in and to United States Patent No. 5,928,204 ("the '204 patent") entitled "Medical Valve and Method of Use." A true and correct copy of the '204 patent is attached hereto as Exhibit E to this Complaint.

27. Upon information and belief, ICU is the owner of the entire right, title, and interest in and to United States Patent No. 5,572,592 ("the '592 patent") entitled "Medical Valve and Method of Use." A true and correct copy of the '592 patent is attached hereto as Exhibit F to this Complaint.

28. On July 27, 2007, ICU filed a Complaint for Patent Infringement against RyMed in the United States District Court for the District of Delaware, C.A. No. 07-468-JJF, alleging that RyMed's InVision-Plus® NEUTRAL® I.V. Connector System infringes the '866 patent,[1] the '862 patent, the '204 patent, and the '592 patent. RyMed must answer, move, or otherwise respond to ICU's Complaint on October 17, 2007. As such, an actual and justiciable controversy exists between RyMed and ICU as to the non-infringement of the InVision-Plus® NEUTRAL® I.V. Connector System of the '866 patent, the '862 patent, the '204 patent, and the '592 patent, as well as the invalidity of those patents.

29. As described above, RyMed has taken ongoing concrete steps with the intent to manufacture, offer to sell and sell in the United States the InVision-Plus® NEUTRAL® with Modified Boot. RyMed intends to begin offering the InVision-Plus® NEUTRAL® with Modified Boot for sale in the first quarter of 2008.

30. Because of similarities in design, purpose, and markets between the InVision-Plus® NEUTRAL® with Modified Boot and the InVision-Plus® NEUTRAL® I.V. Connector System and the infringement lawsuit ICU filed against RyMed in Delaware with respect to the InVision-Plus® NEUTRAL® I.V. Connector System, there is a substantial controversy between RyMed and ICU as to the non-infringement of the InVision-Plus® NEUTRAL® with Modified Boot of the '866 patent, the '862 patent, the '204 patent, and the '592 patent. RyMed is in the position of either continuing to

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[1] ICU's Delaware complaint incorrectly identified United States Patent No. 5,685,866 as United States Patent No. 5,865,866. RyMed assumes that ICU is asserting claims of U.S. Patent No. 5,685,866 against RyMed in the Delaware case.

pursue its plans with respect manufacturing, offering to sell, and selling the InVision-Plus® NEUTRAL® with Modified Boot in the United States under apprehension of suit by ICU, or abandoning its efforts.

31. This is an actual and justiciable controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

COUNT 1

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '866 PATENT BY THE INVISION-PLUS® NEUTRAL® I.V. CONNECTOR SYSTEM

32. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 31 of this Complaint.

33. An actual and justiciable controversy exists between RyMed and ICU as to the non-infringement of the '866 patent by the InVision-Plus® NEUTRAL® I.V. Connector System.

34. RyMed's InVision-Plus® NEUTRAL® I.V. Connector System has not infringed and does not infringe any valid and enforceable claim of the '866 patent, either directly, indirectly, literally, or under the doctrine of equivalents.

35. RyMed has no adequate remedy at law. The actions and assertions made by ICU regarding the infringement of the InVision-Plus® NEUTRAL® I.V. Connector System of the '866 patent have caused and, if not enjoined, will continue to cause irreparable injury to RyMed.

COUNT 2

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '862 PATENT BY THE INVISION-PLUS® NEUTRAL® I.V. CONNECTOR SYSTEM

36. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 35 of this Complaint.

37. An actual and justiciable controversy exists between RyMed and ICU as to the non-infringement of the '862 patent by the InVision-Plus® NEUTRAL® I.V.

Connector System.

38. RyMed's InVision-Plus® NEUTRAL® I.V. Connector System has not infringed and does not infringe any valid and enforceable claim of the '862 patent, either directly, indirectly, literally, or under the doctrine of equivalents.

39. RyMed has no adequate remedy at law. The actions and assertions made by ICU regarding the infringement of the InVision-Plus® NEUTRAL® I.V. Connector System of the '862 patent have caused and, if not enjoined, will continue to cause irreparable injury to RyMed.

COUNT 3

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '204 PATENT BY THE INVISION-PLUS® NEUTRAL® I.V. CONNECTOR SYSTEM

40. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 39 of this Complaint.

41. An actual and justiciable controversy exists between RyMed and ICU as to the non-infringement of the '204 patent by the InVision-Plus® NEUTRAL® I.V. Connector System.

42. RyMed's InVision-Plus® NEUTRAL® I.V. Connector System has not infringed and does not infringe any valid and enforceable claim of the '204 patent, either directly, indirectly, literally, or under the doctrine of equivalents.

43. RyMed has no adequate remedy at law. The actions and assertions made by ICU regarding the infringement of the InVision-Plus® NEUTRAL® I.V. Connector System of the '204 patent have caused and, if not enjoined, will continue to cause irreparable injury to RyMed.

COUNT 4

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '592 PATENT BY THE INVISION-PLUS® NEUTRAL® I.V. CONNECTOR SYSTEM

44. RyMed realleges and incorporates herein by reference the matters alleged

in Paragraphs 1 through 43 of this Complaint.

45. An actual and justiciable controversy exists between RyMed and ICU as to the non-infringement of the '592 patent by the InVision-Plus® NEUTRAL® I.V. Connector System.

46. RyMed's InVision-Plus® NEUTRAL® I.V. Connector System has not infringed and does not infringe any valid and enforceable claim of the '592 patent, either directly, indirectly, literally, or under the doctrine of equivalents.

47. RyMed has no adequate remedy at law. The actions and assertions made by ICU regarding infringement of the InVision-Plus® NEUTRAL® I.V. Connector System of the '592 patent have caused and, if not enjoined, will continue to cause irreparable injury to RyMed.

COUNT 5

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '866 PATENT BY THE INVISION-PLUS® NEUTRAL® WITH MODIFIED BOOT

48. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 47 of this Complaint.

49. An actual and justiciable controversy exists between RyMed and ICU regarding the non-infringement of the '866 patent by the InVision-Plus® NEUTRAL® with Modified Boot.

50. RyMed's InVision-Plus® NEUTRAL® with Modified Boot has not infringed and does not infringe any valid and enforceable claim of the '866 patent, either directly, indirectly, literally, or under the doctrine of equivalents.

51. RyMed has no adequate remedy at law. The threat of actions and assertions by ICU regarding non-infringement by the InVision-Plus® NEUTRAL® with Modified Boot of the '866 patent have caused and, if not enjoined, will continue to cause irreparable injury to RyMed.

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COUNT 6

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '862 PATENT BY THE INVISION-PLUS® NEUTRAL® WITH MODIFIED BOOT

52. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 51 of this Complaint.

53. An actual and justiciable controversy exists between RyMed and ICU regarding the non-infringement of the '862 patent by the InVision-Plus® NEUTRAL® with Modified Boot.

54. RyMed's InVision-Plus® NEUTRAL® with Modified has not infringed and does not infringe any valid and enforceable claim of the '862 patent, either directly, indirectly, literally, or under the doctrine of equivalents.

55. RyMed has no adequate remedy at law. The threat of actions and assertions by ICU regarding non-infringement by the InVision-Plus® NEUTRAL® with Modified Boot of the '862 patent have caused and, if not enjoined, will continue to cause irreparable injury to RyMed.

COUNT 7

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '204 PATENT BY THE INVISION-PLUS® NEUTRAL® WITH MODIFIED BOOT

56. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 55 of this Complaint.

57. An actual and justiciable controversy exists between RyMed and ICU regarding the non-infringement of the '204 patent by the InVision-Plus® NEUTRAL® with Modified Boot.

58. RyMed's InVision-Plus® NEUTRAL® with Modified Boot has not infringed and does not infringe any valid and enforceable claim of the '862 patent, either directly, indirectly, literally, or under the doctrine of equivalents.

59. RyMed has no adequate remedy at law. The threat of actions and

assertions by ICU regarding non-infringement by the InVision-Plus® NEUTRAL® with Modified of the '204 patent have caused and, if not enjoined, will continue to cause irreparable injury to RyMed.

COUNT 8

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '592 PATENT BY THE INVISION-PLUS® NEUTRAL® WITH MODIFIED BOOT

60. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 59 of this Complaint.

61. An actual and justiciable controversy exists between RyMed and ICU regarding the non-infringement of the '592 patent by the InVision-Plus® NEUTRAL® with Modified Boot.

62. RyMed's InVision-Plus® NEUTRAL® with Modified Boot has not infringed and does not infringe any valid and enforceable claim of the '592 patent, either directly, indirectly, literally, or under the doctrine of equivalents.

63. RyMed has no adequate remedy at law. The threat of actions and assertions by ICU regarding non-infringement by the InVision-Plus® NEUTRAL® with Modified Boot of the '592 patent have caused and, if not enjoined, will continue to cause irreparable injury to RyMed.

COUNT 9

DECLARATORY JUDGMENT OF INVALIDITY OF THE '866 PATENT

64. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 63 of this Complaint.

65. An actual and justiciable controversy exists between RyMed and ICU as to the invalidity of the '866 patent.

66. The claims of the '866 patent are invalid and unenforceable for failure to meet one or more of the requirements of patentability specified in Title 35 of the United States Code, including without limitation 35 U.S.C. §§ 102, 103 and/or 112.

67. RyMed has no adequate remedy at law. The actions and assertions made by ICU regarding infringement of the '866 patent have caused and, if not enjoined, will continue to cause irreparable injury to RyMed.

COUNT 10

DECLARATORY JUDGMENT OF INVALIDITY OF THE '862 PATENT

68. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 67 of this Complaint.

69. An actual and justiciable controversy exists between RyMed and ICU as to the invalidity of the '862 patent.

70. The claims of the '862 patent are invalid and unenforceable for failure to meet one or more of the requirements of patentability specified in Title 35 of the United States Code, including without limitation 35 U.S.C. §§ 102, 103 and/or 112.

71. RyMed has no adequate remedy at law. The actions and assertions made by ICU regarding infringement of the '862 patent have caused and, if not enjoined, will continue to cause irreparable injury to RyMed.

COUNT 11

DECLARATORY JUDGMENT OF INVALIDITY OF THE '204 PATENT

72. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 71 of this Complaint.

73. An actual and justiciable controversy exists between RyMed and ICU as to the invalidity of the '204 patent.

74. The claims of the '204 patent are invalid and unenforceable for failure to meet one or more of the requirements of patentability specified in Title 35 of the United States Code, including without limitation 35 U.S.C. §§ 102, 103 and/or 112.

75. RyMed has no adequate remedy at law. The actions and assertions made by ICU regarding infringement of the '204 patent have caused and, if not enjoined, will continue to cause irreparable injury to RyMed.

COUNT 12

DECLARATORY JUDGMENT OF INVALIDITY OF THE '592 PATENT

76. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 75 of this Complaint.

77. An actual and justiciable controversy exists between RyMed and ICU as to the invalidity of the '592 patent.

78. The claims of the '592 patent are invalid and unenforceable for failure to meet one or more of the requirements of patentability specified in Title 35 of the United States Code, including without limitation 35 U.S.C. §§ 102, 103 and/or 112.

79. RyMed has no adequate remedy at law. The actions and assertions made by ICU regarding infringement of the '592 patent have caused and, if not enjoined, will continue to cause irreparable injury to RyMed.

COUNT 13

FEDERAL TRADEMARK INFRINGEMENT (Lanham Act, 15 U.S.C. § 1114)

80. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 79 of this Complaint.

81. RyMed owns the goodwill symbolized by its NEUTRAL® mark. The use of each NEUTRAL® mark substantially increases the value of RyMed and the salability of the goods sold, and services offered, under the NEUTRAL® mark.

82. ICU either had actual notice and knowledge, or had constructive notice, of RyMed's ownership and registration of the NEUTRAL® mark pursuant to 15 U.S.C. § 1072 prior to ICU's incorporation and use of the mark in the name of its products.

83. RyMed has not consented to ICU's use of its NEUTRAL® mark.

84. Upon information and belief, ICU deliberately and willfully used and is using in commerce a reproduction, copy, or colorable imitation of the NEUTRAL® mark in connection with the sale, offering for sale, distribution, or advertising of ICU's

products in an attempt to trade on the goodwill, reputation, and selling power established by RyMed under the NEUTRAL® mark.

85. Upon information and belief, the products sold by ICU using the NEUTRAL® mark have moved, are moving, and will continue to move through the same channels of trade and to the same consumers as RyMed's products that are sold under the NEUTRAL® mark.

86. ICU's unauthorized use of the NEUTRAL® mark is likely to cause confusion, or likely to cause mistake, or to deceive consumers or potential consumers wishing to purchase RyMed's products.

87. ICU's unauthorized use of the NEUTRAL® mark is likely to falsely indicate to consumers that ICU's products are in some manner connected with, sponsored by, affiliated with, or related to RyMed and its products.

88. ICU's unauthorized use of the NEUTRAL® mark is likely to cause consumers to be confused as to the source, nature, and quality of the products ICU is promoting or selling.

89. ICU's unauthorized use of the NEUTRAL® mark in connection with the sale of its products allowed, allows, and will continue to allow, ICU to receive the benefit of the goodwill established at great labor and expense by RyMed and to gain acceptance of ICU's products, not based on the merits of those products, but on RyMed's reputation and goodwill.

90. ICU's unauthorized use of the NEUTRAL® mark in connection with the sale of its products is likely to deprive RyMed of the ability to control the consumer perception of the quality of the products marketed under the NEUTRAL® mark, and places RyMed's valuable reputation and goodwill in the hands of ICU, over whom RyMed has no control.

91. Upon information and belief, ICU intended and intends its unauthorized use of the NEUTRAL® mark to cause confusion, or to cause mistake, or to deceive.

92. ICU's acts constitute federal trademark infringement in violation of 15 U.S.C. § 1114.

93. The intentional nature ICU's acts makes this an exceptional case pursuant to 15 U.S.C. § 1117(a).

94. RyMed has been, is now, and will be irreparably injured by ICU's trademark infringement, and unless enjoined by this Court, RyMed will suffer further harm to its name, reputation and goodwill. This harm constitutes an injury for which RyMed has no adequate remedy at law.

COUNT 14

FEDERAL FALSE DESIGNATION OF ORIGIN (Lanham Act § 43(a); 15 U.S.C. § 1125(a))

95. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 94 of this Complaint.

96. ICU's unauthorized use of the NEUTRAL® mark in commerce in connection with its goods falsely suggests that ICU's goods are connected with, sponsored by, affiliated with, approved by, or otherwise related to RyMed.

97. ICU's unauthorized use of the NEUTRAL® mark is likely to cause further confusion, or to cause mistake, or to deceive consumers or potential consumers wishing to purchase RyMed's products that ICU's goods are connected with, sponsored by, affiliated with, approved by, or otherwise related to RyMed.

98. ICU's unauthorized use of the NEUTRAL® mark constitutes a false designation of origin in violation of 15 U.S.C. § 1125(a).

99. The intentional nature of the ICU's acts makes this an exceptional case pursuant to 15 U.S.C. § 1117(a).

100. RyMed has been, is now, and will continue to be irreparably injured and damaged by ICU's trademark infringement insofar as the public has been and/or is deceived into believing that the products marketed by ICU are connected with, sponsored by, affiliated with, or related to RyMed.

101. RyMed has been, is now, and will continue to be irreparably injured by ICU's acts, and unless enjoined by this Court, RyMed will suffer further harm to its name, reputation and goodwill. This harm constitutes an injury for which RyMed has no adequate remedy at law.

COUNT 15

FEDERAL UNFAIR COMPETITION (Lanham Act § 43(a); 15 U.S.C. § 1125(a))

102. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 101 of this Complaint.

103. ICU's unauthorized use of the NEUTRAL® mark in commerce in connection with its goods falsely or misleadingly describes or represents that ICU's products have zero fluid displacement.

104. ICU's unauthorized use of the NEUTRAL® mark in commercial advertising or promotion misrepresents the nature, characteristics, and qualities of ICU's goods.

105. ICU has also used, made, approved, and sponsored false and misleading representations in advertising and other promotional materials that discredit and disparage RyMed's products, misrepresent ICU's products, and misrepresent the FDA's investigation of RyMed and RyMed's voluntary recall of specific lots of its InVision-Plus® NEUTRAL® I.V. Connector System, and ICU continues to make such false and misleading statements with specific intent that they deceive and mislead consumers and potential consumers of intravenous catheter safety products and the general public.

106. ICU's false and misleading statements have been placed in interstate commerce, have actually deceived consumers and the public, create a likelihood that a substantial segment of consumers and the public will be deceived, have substantially damaged RyMed, and violate 15 U.S.C. § 1125(a).

107. The intentional nature of the ICU's acts makes this an exceptional case pursuant to 15 U.S.C. § 1117(a).

108. RyMed has been, is now, and will be irreparably injured by ICU's acts, and unless enjoined by this Court, RyMed will suffer further harm to its name, reputation and goodwill. This harm constitutes an injury for which RyMed has no adequate remedy at law.

COUNT 16

STATE TRADEMARK INFRINGEMENT (CAL. BUS. & PROF. CODE SECTION 14335)

109. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 108 of this Complaint.

110. ICU's has used or is using RyMed's NEUTRAL® mark in connection with its goods without the prior consent of RyMed.

111. ICU's has unlawfully infringed and is unlawfully infringing RyMed's NEUTRAL® mark without the prior consent of RyMed.

112. ICU's acts constitute trademark infringement in violation of California Business and Professional Code Section 14335, as they are likely to deceive the public.

113. ICU's acts of trademark infringement have caused and will continue to cause RyMed irreparable harm. RyMed has no adequate remedy at law for ICU's trademark infringement.

114. RyMed is entitled to a judgment enjoining and restraining ICU from engaging in further infringement.

COUNT 17

COMMON LAW PASSING OFF AND UNFAIR COMPETITION

115. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 114 of this Complaint.

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116. RyMed owns and has used the NEUTRAL® mark, as a distinctive trademark throughout the United States for more than three-and-a-half years. This mark is a valid trademark under state common law.

117. ICU's unauthorized use of the term Neutral constitutes infringement and unfair competition of the NEUTRAL® mark in violation of the common law of California.

118. ICU's wrongful acts have caused and will continue to cause RyMed irreparable harm. RyMed has no adequate remedy at law.

119. RyMed is entitled to a judgment enjoining and restraining ICU from engaging in further acts of infringement and unfair competition.

COUNT 18

STATE UNFAIR COMPETITION (CAL. BUS. & PROF. CODE SECTION 17200)

120. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 119 of this Complaint.

121. ICU's unlawful, unfair and/or fraudulent business acts and practices described herein constitute unfair competition in violation of Section 17200 *et seq.* of the California Business & Professions Code.

122. ICU's acts and practices as described herein have deceived and/or are likely to deceive members of the consuming public.

123. ICU's acts of unfair competition have caused and will continue to cause RyMed irreparable harm. RyMed has no adequate remedy at law for ICU's unfair competition.

124. RyMed is entitled to a judgment enjoining and restraining ICU from engaging in further unfair competition, and is further entitled to an award of restitution for ICU's unjust enrichment.

COUNT 19

STATE UNFAIR COMPETITION (CAL. BUS. & PROF. CODE SECTION 17500)

125. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 124 of this Complaint.

126. ICU purposefully and intentionally made or disseminated or caused to be made or disseminated to the public unfair, deceptive, untrue and/or misleading statements and advertising in violation of Section 17500 *et seq.* of the California Business & Professions Code.

127. In making and disseminating the statements and advertisements described herein, ICU knew or should have known that the statements and advertising were untrue or misleading, and were in violation of California Business & Professions Code Section 17500 *et seq.*

128. ICU's acts have substantially damaged RyMed's business, substantially damaged consumers' interests, and unjustly enriched ICU, and will continue to do so unless enjoined by the Court.

129. ICU's acts have caused and will continue to cause RyMed irreparable harm. RyMed has no adequate remedy at law for ICU's wrongful conduct.

130. RyMed is entitled to a judgment enjoining and restraining ICU from engaging in further wrongful conduct, and is further entitled to an award of restitution for ICU's unjust enrichment.

COUNT 20

INTENTIONAL INTERFERENCE WITH CONTRACT

131. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 130 of this Complaint.

132. RyMed and Co-Medical had a valid distribution agreement.

133. Upon information and belief, ICU knew of this distribution agreement.

134. Through the unfair, unlawful, and fraudulent acts and practices discussed herein, and through other intentional acts according to proof, ICU intended to disrupt this existing contractual relationship.

135. ICU's intentional interference disrupted the distribution agreement, and has substantially damaged RyMed's business in an amount to be determined at trial.

136. ICU's interference with the Co-Medical distribution agreement was and is oppressive, fraudulent, and malicious and was and is intended to obtain an unfair and improper competitive advantage such that RyMed is entitled to recover punitive damages against ICU in an amount to be determined at trial.

COUNT 21

INTENTIONAL INTERFERENCE WITH PROSPECTIVE BUSINESS AND ECONOMIC ADVANTAGES

137. RyMed realleges and incorporates herein by reference the matters alleged in Paragraphs 1 through 136 of this Complaint.

138. RyMed had economic relationships with potential customers that possessed the probability of future economic benefit for RyMed.

139. ICU knew about these relationships.

140. ICU engaged in independently wrongful, unfair, unlawful, and fraudulent acts and practices as described herein designed to interfere with or disrupt these relationships.

141. ICU intended to disrupt and interfere with these relationships through its unfair, unlawful, and fraudulent acts and practices described herein, or had knowledge that its interference or disruption was certain or substantially certain to occur as a result of its actions.

142. ICU's intentional interference disrupted prospective customer relationships and other prospective economic advantages, and has substantially damaged RyMed's business in an amount to be determined at trial.

e. A judgment ordering ICU, pursuant to 15 U.S.C. § 1116(a), to file with this Court and serve upon RyMed within thirty (30) days after entry of the injunction, a report in writing under oath setting forth in detail the manner and form in which ICU has complied with the injunction, ceased all sales of goods and services under the NEUTRAL® mark as set forth above;

f. A judgment ordering ICU, pursuant to 15 U.S.C. § 1118, to deliver up for destruction, or to show proof of said destruction or sufficient modification to eliminate the infringing matter, all articles, packages, wrappers, products, displays, labels, signs, circulars, kits, packaging, letterheads, business cards, promotional items, literature, sales aids, receptacles or other matter in the possession, custody, or under the control of ICU or its agents bearing the NEUTRAL® mark in any manner, or any mark that is confusingly similar to or a colorable imitation of this mark, including without limitation the term NEUTRAL®, both alone and in combination with other words or terms, and all plates, molds, matrices, and other means of making the same;

g. A judgment that ICU account for and disgorge to RyMed all of the profits realized by ICU, or others acting in concert or participating with ICU relating to ICU's use of the NEUTRAL® mark and as the Court may deem appropriate, any additional amounts pursuant to 15 U.S.C. § 1117, plus interest;

h. A judgment requiring that ICU and its officers, agents, servants, employees, owners and representatives, and all other persons, firms or corporations in active concert or participation with it, be enjoined and restrained from committing further unfair competition, passing off, tortious interference, and Lanham Act violations;

i. Actual damages according to proof for ICU's common law passing off and unfair competition, intentional interference with contract, and intentional interference with prospective business and economic advantages, and Lanham Act violations;

j. Restitution and recovery of ICU's unjust enrichment;

k. Prejudgment interest;

l. Exemplary damages;

m. Reasonable attorneys' fees pursuant to 15 U.S.C. § 1117(a);

n. A judgment declaring this case to be an exceptional case within the meaning of 35 U.S.C. § 285, and awarding RyMed its attorneys' fees, costs, and expenses incurred in this action as permitted by law; and

o. Such other and further relief as the Court may deem just and proper.

DATED: October 10, 2007

Respectfully submitted,

HOWREY LLP

By: _____
Don Livornese

Attorney for Plaintiff
RYMED TECHNOLOGIES, INC.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff RyMed hereby demands a trial by jury of this action.

DATED: October 10, 2007

Respectfully submitted,

HOWREY LLP

By: _____
Don Livornese

Attorney for Plaintiff
RYMED TECHNOLOGIES, INC.

EXHIBIT I

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Attorneys for Plaintiff
RYMED TECHNOLOGIES, INC.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SACV07-1199

RYMED TECHNOLOGIES, INC., a Delaware corporation,

Plaintiff,

vs.

ICU MEDICAL, INC., a Delaware corporation,

Defendant.

Case No.

NOTICE OF RELATED CASES

NOTICE OF PENDENCY OF OTHER ACTIONS OR PROCEEDINGS

Pursuant to Civil L. R. 83-1.3.1 and 83.1.4.1-2 of the United States District Court for the Central District of California, Plaintiff RyMed Technologies, Inc. ("RyMed")

submits the following Notice of Related Cases and Notice of Pendency of Other Actions or Proceedings.

On October 10, 2007, RyMed filed this instant case against ICU Medical, Inc. ("ICU"). The Complaint includes claims for: (i) declaratory judgment that U.S. patents 5,685,866 ("the '866 patent"), 5,873,862 ("the '862 patent"), 5,928,204 ("the '204 patent"), and 6,572,592 ("the '592 patent") are not infringed by RyMed's current product, the In-Vision Plus® Neutral® I.V. Connector System; (ii) declaratory judgment that the '866 patent, the '862 patent, the '204 patent, and the '592 patent are not infringed by RyMed's newly developed product, In-Vision Plus® Neutral® with Modified Boot; (iii) declaratory judgment that the '866 patent, the '862 patent, the '204 patent, and the '592 patent are invalid and unenforceable; (iv) violations of the Lanham Act, 15 U.S.C. § 1114; (v) violations of the Lanham Act, 15 U.S.C. § 1125(a); (vi) violations of Cal. Bus. & Prof. Code section 14335; (vii) common law passing off and unfair competition; (viii) violations of Cal. Bus. & Prof. Code section 17200; (ix) violations of Cal. Bus. & Prof. Code section 17500; (x) intentional interference with contract; and (xi) intentional interference with prospective business and economic advantages.

I. RELATED CASES

Under Civ. L.R. 83-1.3.1, cases are related if any action previously filed or currently pending in the Central District and the action being filed appear:

(a) to arise from the same or a closely related transaction, happening or event;

(b) to call for determination of the same or substantially related or similar questions of law and fact;

(c) for other reasons would entail substantial duplication of labor if heard by different judges; or

(d) to involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c is present.

All four factors apply here.

A. *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*, Case No. CV 04-00689 (MRP)

The first related case, *ICU Medical, Inc. v. Alaris Medical Systems, Inc.* (Case No. CV 04-00689 (MRP)), was filed in the Central District of California. Judge Mariana Pfaelzer issued a claim construction order in that case on July 17, 2006, and granted partial summary judgment of noninfringement in August 2006. In February 2007, Judge Pfaelzer further granted summary judgment of invalidity of certain claims of the '592 patent. Judge Pfaelzer issued a final judgment in favor of Alaris on September 21, 2007. That case involved three of the four patents (the '866, the '862, and the '592 patents) for which RyMed seeks declaratory judgment of non-infringement and invalidity in this pending Central District case.

B. *Medegen MMS, Inc. v. ICU Medical, Inc.*, Case No. CV-06-619 (MRP)

Judge Mariana Pfaelzer also presided over a second related case, *Medegen MMS, Inc. v. ICU Medical, Inc.* (Case No. CV-06-619 (MRP)), filed in the Central District of California. On June 5, 2007, a Markman hearing was held to construe claim terms, after which the plaintiff dismissed most of the asserted patent claims. On September 14, 2007, Judge Pfaelzer granted summary judgment of non-infringement of the remaining claims. That case did not involve the same patents as this pending Central District action (or the *ICU Medical v. Alaris Medical Systems* action), but the patent (U.S. patent 5,730,418) and accused products in *Medegen* concerned the same general technical field as the technology at issue in this Central District action (*i.e.*, a minimum fluid displacement needleless connector that interfaces with an IV catheter).

II. OTHER PENDING ACTIONS

A. *ICU Medical, Inc. v. RyMed Technologies, Inc.*, Case No. CA-07-468-JJF

A third potentially related case, *ICU Medical, Inc. v. RyMed Technologies, Inc.* (Case No. CA-07-468-JJF), was filed in the United States District Court for the District of Delaware on July 27, 2007. A copy of the complaint for that action is attached (without exhibits) as Exhibit A. The parties have stipulated to extend time for filing a response until October 17, 2007. RyMed immediately intends to file a Motion to Transfer Venue to the Central District of California pursuant to 28 U.S.C. § 1404(a).

In the pending Delaware case, ICU alleges that RyMed's commercially available In-Vision Plus® Neutral® IV Connector System infringes the four patents at issue in the pending Central District action. Events underlying the federal and state counts in the pending Central District action and the federal counts in the pending Delaware action arose in the Central District of California, ICU's principal place of business. Both the pending Central District and Delaware actions will require a determination of the validity of the four patents assigned to and asserted by ICU. RyMed's attorneys for the pending Delaware case are identical to its attorneys for this Central District action, and their contact information is listed on the caption page. Counsel for ICU is identified on the attached copy of the complaint (Exhibit A), with their accompanying contact information.

III. JUDICIAL ECONOMY FAVORS ASSIGNMENT TO JUDGE PFAELZER

Judicial economy favors assignment of this case to Judge Mariana Pfaelzer for several reasons:

First, the two related cases in the Central District, the pending Delaware action, and the pending Central District action concern the same technology: a minimum fluid displacement needleless connector that interfaces with an IV catheter. Resolution of these disputes will require an understanding of and familiarity with needleless access connectors that interface with an intravenous catheter to deliver fluid to a patient. Judge Pfaelzer of the Central District has already committed significant judicial resources to understanding this subject matter and construing claims in the two recently resolved

patent litigation actions (*Alaris* and *Medgen MMS*) in the Central District, including construction of claim terms from three of the four patents at issue in this case.

Second, ICU is a party litigant in the instant suit, as well as in each of the related cases and the pending Delaware case.

Finally, the pending Central District and Delaware actions concern the identical four patents assigned to and asserted by ICU, so resolution of both disputes will require a determination of many of the same questions of fact and law, including the invalidity of the patents in suit.

In sum, this pending case should be assigned to Judge Mariana Pfaelzer due to her substantial expertise and continuing efforts regarding the patents and technology at issue. Assignment of this case to another judge would necessarily and substantially duplicate efforts already expended by Judge Pfaelzer.

III. CONCLUSION

For the foregoing reasons, RyMed believes that the above discussed cases are related, and that assignment of this newly filed case to Judge Mariana R. Pfaelzer is appropriate.

DATED: October 10, 2007

Respectfully submitted,

HOWREY LLP

By: _____

Don Livornese

Attorney for Plaintiff
RYMED TECHNOLOGIES, INC.

EXHIBIT J

Westlaw.
Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2006 WL 2038504 (D.Del.)
(Cite as: Not Reported in F.Supp.2d)

H

Cashedge, Inc. v. Yodlee, Inc.
D.Del.,2006.
Only the Westlaw citation is currently available.
United States District Court,D. Delaware.
CASHEDGE, INC., Plaintiff,
v.
YODLEE, INC., Defendant.
No. Civ.A.06-170 JJF.

July 19, 2006.

Arthur G. Connolly, III, of Connolly Bove Lodge & Hutz LLP, Wilmington, Delaware, Drew M. Wintringham, III, and Mark W. Rueh, of Clifford Chance Rogers & Wells LLP, New York City, New York, for Plaintiff, of Counsel.
William J. Marsden, Jr., and Kyle Wagner Compton, of Fish & Richardson, P.C., Wilmington, Delaware, David M. Barken, and Craig R. Compton, of Fish & Richardson, P.C., Redwood City, California, for Defendant, of Counsel.

MEMORANDUM OPINION

FARNAN, J.

***1** Pending before the Court is Defendant's Motion To Transfer (D.I.12). For the reasons discussed, the Motion will be granted.

I. BACKGROUND

Plaintiff was issued United States Patent No. 7,013,310 ("the '310 patent"), entitled "Method And Apparatus For Retrieving And Processing Data" on March 14, 2006. That same day, Plaintiff filed its Complaint in this Court, alleging infringement of the '310 patent. (D.I.1). Defendant filed its Answer and Counterclaim on April 4, 2006, and stated its intent to file a motion to transfer. (D.I.5). On May 4, 2006, Defendant filed its Motion to Transfer. (D .I. 12).

Defendant's Motion to Transfer is based on a pending action in the Northern District of California, Case No. C-05-1550-SI. On April 14, 2005, Defendant filed a patent infringement action in the Northern District of California, alleging that Plaintiff infringed several of its U.S. Patents. In response, Plaintiff filed an action in the same court, seeking a declaratory judgment of non-infringement, invalidity, and unenforceability of the patents asserted in Defendant's case and additional patents. Those two actions were consolidated into one nine-patent case ("the California action"). The California court conducted a Markman hearing on April 26, 2006.

II. PARTIES' CONTENTIONS

By its Motion, Defendant contends that, pursuant to 28 U.S.C. § 1404(a), the Court should transfer this action to the Northern District of California. In support of this contention, Defendant argues that Plaintiff's allegations of infringement of the '310 patent are related to the allegations in the California action. Further, Defendant contends that certain patents in the California action are prior art to Plaintiff's '310 patent and form the basis of Defendant's inequitable conduct defense.[FN1] In response, Plaintiff contends that the Court should deny the Motion because Plaintiff chose Delaware, the California action is unrelated, and judicial economy would not be served by transfer.

FN1. Defendant alleges that, at a minimum, United States Patent Nos. 6,317,783 ("the '783 patent"), 6,199,077 ("the '077 patent"), and 6,412,073 ("the '073 patent") are material prior art to Plaintiff's '310 patent. (D.I. 5 at ¶ 23).

III. DISCUSSION

Under 28 U.S.C. § 1404(a), "[f]or the convenience of the parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought." 28 U.S.C. § 1404(a). Since it is undisputed that Plaintiff could have brought the instant action in the Northern District of California, the Court's only task is to determine whether the factors enumerated in Section 1404(a) warrant a transfer under the circumstances.

The Third Circuit has set forth a list of factors for district courts to consider when deciding whether or not to transfer venue. *Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879-80 (3d Cir.1995). These factors include six private interests: (1) the plaintiff's forum preference as evidenced by his or her original choice,

(2) the defendant's preference, (3) whether the claim arose elsewhere, (4) the convenience of the parties due to their relative physical and financial condition, (5) the convenience of the expected witnesses, but only so far as the witnesses might be unavailable for trial if the trial is conducted in a certain forum, and (6) the location of books and records, to the extent that the books and records could not be produced in a certain forum. *Id.* at 879. The factors also include six public interests for courts to consider: (1) the enforceability of the judgment, (2) practical considerations regarding the ease, speed, or expense of trial, (3) the administrative difficulty due to court congestion, (4) the local interest in deciding local controversies in the home forum, (5) the public policies of the two fora, and (6) the trial judge's familiarity with the applicable state law in diversity cases. *Id.* at 879-80. District courts must balance all of the relevant factors and determine whether a transfer of venue would best serve all the aforementioned interests. *Id.* at 883. The burden is on the movant to establish that the balance of the interests weighs in favor of the requested transfer, and a transfer will be denied if the factors are evenly balanced or weigh only slightly in favor of the transfer. *Continental Cas. Co. v. Am. Home Assurance Co.*, 61 F.Supp.2d 128, 131 (D.Del.1999).

A. *PRIVATE INTERESTS*

***2** Although the plaintiff's choice of forum is entitled to substantial deference and should not be lightly disturbed, *Shutte v. Armco Steel Corp.*, 431 F.2d 22, 25 (3d Cir.1920), when the plaintiff lacks a rational and legitimate reason to litigate in the forum, the transfer of a case to a more appropriate forum is less inconvenient. *Brunswick Corp. v. Precor Inc.*, 2000 U.S. Dist. LEXIS 22222, at *7 (D.Del. Dec. 12, 2000); *See Waste Distillation Tech., Inc. v. Pan Am. Res., Inc.*, 775 F.Supp. 759, 764 (D.Del.1991). A corporation's decision to incorporate in a particular state is a rational and legitimate reason to choose to litigate in that state. *Stratos Lightwave, Inc. v. E2O Communs., Inc.*, 2002 U.S. Dist. LEXIS 5653, C.A. No. 01-309 JJF, at *7 (D.Del. March 26, 2002). Accordingly, the first factor weighs against transfer, and Defendant must demonstrate that the other *Jumara* factors strongly favor a transfer to California.

The Court concludes that the other private interest factors weigh in favor of transfer. Here, both parties are Delaware corporations with principal places of business outside Delaware. Plaintiff is headquartered in New York City, and Defendant is headquartered in Redwood City, California. Both parties maintain offices in the Northern District of California. Also, there are likely witnesses, such as former employees, that still reside in the Northern District of California. The location of books and records is neutral as neither party has argued that it would be unable to produce documents in either forum.

Importantly, the same parties are currently litigating in the Northern District of California. Although the Court understands that the California action and this action are different,[FN2] the technologies at issue all relate to data extraction, retrieval, or presentation through Internet technologies, such as web sites and web pages. The Northern District of California is more convenient for the parties because the parties and potential witnesses are located in that district, the parties have proven capable to litigate there, and the court is already familiar with the parties and their technologies.

FN2. This action requires claim construction of the claim language of the '310 patent, which is not part of the California action. However, Defendant's patents-in-suit in the California action are relevant to its defenses and counterclaim in this action.

B. *PUBLIC INTERESTS*

The Court also concludes that the public interest factors weigh in favor of transfer. Where related lawsuits exist, "it is in the interests of justice to permit suits involving the same parties and issues to proceed before one court." *Brunswick,* 2000 U.S. Dist. LEXIS 22222, at *8. Factors supporting a decision to transfer include whether the litigation in the target forum involves: (1) the same parties, (2) related or similar technologies for the judge to become familiar with, and (3) a common field of prior art.

In this case, judicial efficiency regarding the ease, speed, or expense of trial strongly weigh in favor of transfer. The California action involves the same parties, similar technologies, and related patents-in-suit. The parties in the California action have already conducted a two-hour technology tutorial on April 19, 2006, argued Markman issues in nine patents on April 26, 2006, and commenced discovery on seemingly related products and technologies. Additionally, the Court concludes that public interests such as enforceability of the judgment, familiarity with state law in diversity actions, local

interests in deciding local controversies, and court congestion are neutral or non-applicable factors in this case. *Jumara,* 55 F.3d at 879-880. Accordingly, the interests of judicial efficiency and justice are best served by transferring this case to the Northern District of California.

IV. CONCLUSION

***3** In sum, for the reasons discussed, the Court concludes that the balance of the private and public interest factors support transferring this case to the Northern District of California where related litigation is pending. Accordingly, the Court will grant Defendant's Motion To Transfer (D.I.12).

An appropriate Order will be entered.

ORDER

At Wilmington, the *19* day of July 2006, for the reasons set forth in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that the Defendant's Motion To Transfer (D.I.12) is *GRANTED.*

D.Del.,2006.
Cashedge, Inc. v. Yodlee, Inc.
Not Reported in F.Supp.2d, 2006 WL 2038504 (D.Del.)

END OF DOCUMENT

EXHIBIT K

ICU Medical, Inc.

I ICU Medical Products About ICU Medical Inve World Leader in Safety Medical Systems

About ICU Medical, Inc.

ICU Medical, Inc.

ICU Medical was founded in 1984 by Dr. George Lopez, a practicing internist who imagined that there must be a better way of securing I.V. lines after tragically losing a patient due to an accidental disconnect. Dr. Lopez conceived a product, later known as the Click Lock, which provided a locking mechanism for these I.V. systems. The Click Lock was comprised of a protected needle which would also serve to prevent health care workers from being accidentally stuck by the I.V. needles.

Today, with a market cap of close to 500 million ICU has an impressive list of landmark products including the CLAVE NeedleFree Connector and the CLC2000 Catheter Patency Device.

Still led by Dr. Lopez, ICU is solely focused on developing and manufacturing products that not only protect the Health Care worker from accidental needlesticks, but protect the integrity of the patient's IV system as well.

EXHIBIT L

Table C-5.
U.S. District Courts—Median Time Intervals From Filing to Disposition of Civil Cases Terminated, by District and Method of Disposition, During the 12-Month Period Ending December 31, 2006

Circuit and District	Total Cases		No Court Action		Court Action					
					Before Pretrial		During or After Pretrial		Trial	
	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months
TOTAL	**199,382**	**7.9**	**46,750**	**6.5**	**125,528**	**7.9**	**23,926**	**15.7**	**3,178**	**23.6**
DC	**2,149**	**10.5**	**883**	**11.1**	**1,202**	**9.8**	**32**	**18.0**	**32**	**37.5**
1ST	**5,280**	**9.5**	**1,998**	**7.7**	**2,254**	**8.5**	**872**	**15.9**	**156**	**26.0**
ME	370	7.0	169	5.2	171	7.2	17	14.0	13	17.0
MA	2,762	9.1	1,334	8.2	940	8.2	388	14.7	100	26.4
NH	437	8.5	142	4.5	118	5.4	172	13.1	5	-
RI	514	8.4	113	5.2	251	8.6	136	12.5	14	22.0
PR	1,197	12.0	240	8.4	774	10.2	159	22.6	24	37.0
2ND	**18,416**	**9.6**	**5,174**	**7.4**	**10,651**	**9.7**	**2,314**	**14.1**	**277**	**30.8**
CT	2,012	11.7	1,340	9.2	567	16.5	59	23.0	46	30.0
NY,N	939	13.9	185	6.2	461	10.7	270	19.6	23	42.5
NY,E	5,272	10.8	1,046	7.0	3,300	9.5	857	15.7	69	32.0
NY,S	8,679	8.9	2,276	7.8	5,320	8.0	962	11.0	121	25.5
NY,W	1,242	11.1	297	6.9	776	11.2	158	25.3	11	53.0
VT	272	9.5	30	5.4	227	9.8	8	-	7	-
3RD	**37,084**	**1.0**	**3,820**	**5.7**	**29,999**	**1.0**	**2,949**	**13.3**	**316**	**25.5**
DE	919	17.9	127	8.0	596	13.1	148	20.6	48	30.0
NJ	5,400	7.6	1,793	6.8	2,120	5.5	1,422	14.2	65	32.5
PA,E	26,785	1.0	772	3.1	24,654	1.0	1,245	10.0	114	18.0
PA,M	1,635	6.2	553	4.6	987	6.0	55	17.4	40	24.5
PA,W	2,073	8.4	539	5.5	1,445	10.5	42	25.3	47	27.0
VI	272	20.0	36	8.0	197	19.5	37	38.0	2	-
4TH	**12,693**	**7.2**	**3,524**	**6.9**	**7,772**	**7.6**	**1,186**	**8.2**	**211**	**19.1**
MD	2,676	7.2	1,235	7.7	1,132	6.5	268	9.2	41	24.0
NC,E	929	11.1	416	10.3	499	12.4	4	-	10	22.0
NC,M	735	10.4	231	6.6	368	12.6	122	12.8	14	21.0
NC,W	877	9.9	342	11.0	439	5.4	88	14.7	8	-
SC	2,727	9.1	375	3.6	2,147	9.4	150	13.0	55	26.0
VA,E	2,599	4.7	544	3.8	1,488	4.4	524	7.9	43	9.4
VA,W	710	8.4	169	7.2	505	8.6	15	9.0	21	18.0
WV,N	410	11.0	151	9.0	244	12.5	9	-	6	-
WV,S	1,030	6.9	61	3.3	950	6.0	6	-	13	21.0

Table C-5. (December 31, 2006—Continued)

Circuit and District	Total Cases		No Court Action		Court Action					
					Before Pretrial		During or After Pretrial		Trial	
	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months
5TH	**21,201**	**8.4**	**4,983**	**6.5**	**13,440**	**8.8**	**2,350**	**13.2**	**428**	**20.9**
LA,E	3,264	9.7	121	2.9	1,751	5.8	1,323	15.6	69	19.5
LA,M	759	11.9	208	5.0	516	11.9	25	24.5	10	24.0
LA,W	1,555	12.9	502	9.3	981	12.4	33	21.4	39	26.0
MS,N	901	12.6	192	5.3	570	12.1	113	17.4	26	21.8
MS,S	3,631	6.5	1,696	6.3	1,853	6.9	39	22.0	43	20.5
TX,N	2,845	7.6	146	6.3	2,639	7.6	3	-	57	21.0
TX,E	1,734	10.5	350	5.8	1,299	10.1	44	12.7	41	19.0
TX,S	4,162	8.6	1,158	5.0	2,160	7.6	752	10.7	92	19.3
TX,W	2,350	9.3	610	7.3	1,671	10.8	18	16.0	51	16.0
6TH	**18,844**	**10.3**	**3,692**	**5.1**	**11,175**	**11.5**	**3,695**	**12.1**	**282**	**24.4**
KY,E	1,742	10.3	217	5.6	1,490	10.1	21	21.0	14	19.4
KY,W	1,230	8.6	213	8.7	891	7.8	112	18.4	14	20.0
MI,E	3,892	9.5	750	4.4	1,326	6.5	1,755	11.0	61	23.0
MI,W	865	8.3	136	3.5	705	8.9	10	19.0	14	19.5
OH,N	5,722	13.1	877	5.2	3,969	19.9	828	10.0	48	19.5
OH,S	2,223	12.3	894	8.0	817	12.9	472	14.1	40	28.5
TN,E	1,114	12.9	152	5.0	476	9.6	455	15.0	31	21.0
TN,M	1,154	10.5	100	3.9	1,012	11.4	13	16.0	29	22.5
TN,W	902	12.4	353	9.7	489	12.6	29	24.0	31	29.4
7TH	**12,784**	**7.9**	**3,926**	**5.1**	**7,269**	**8.3**	**1,357**	**12.2**	**232**	**27.3**
IL,N	6,418	6.5	2,321	5.3	3,519	6.3	478	12.0	100	30.0
IL,C	706	9.1	302	9.0	381	9.5	10	22.0	13	25.0
IL,S	809	8.9	222	6.4	547	8.1	18	16.2	22	20.5
IN,N	1,273	9.7	308	6.8	664	9.4	279	15.6	22	22.0
IN,S	2,064	10.5	548	7.2	1,196	10.0	293	13.6	27	26.0
WI,E	1,063	8.7	172	4.0	774	8.5	84	15.8	33	66.4
WI,W	451	4.7	53	2.0	188	3.6	195	5.5	15	12.7
8TH	**15,250**	**12.0**	**4,054**	**5.1**	**6,065**	**9.1**	**4,867**	**37.0**	**264**	**21.1**
AR,E	1,416	13.1	292	12.7	1,061	13.6	10	14.0	53	19.3
AR,W	731	11.4	53	9.0	626	11.7	28	1.0	24	14.8
IA,N	470	10.0	60	5.8	387	9.2	4	-	19	21.0
IA,S	606	11.9	101	9.3	340	8.9	145	16.3	20	21.0
MN	7,032	31.9	1,722	3.6	668	5.1	4,609	37.3	33	29.7
MO,E	2,039	7.7	736	7.0	1,255	7.0	3	-	45	21.0
MO,W	1,792	8.1	871	6.3	879	9.0	19	19.5	23	23.0
NE	717	8.3	36	1.0	614	8.5	35	17.0	32	20.0
ND	201	11.2	72	6.0	112	12.7	4	-	13	23.0
SD	246	10.4	111	10.4	123	9.5	10	19.0	2	-

Table C-5. (December 31, 2006—Continued)

Circuit and District	Total Cases		No Court Action		Court Action					
					Before Pretrial		During or After Pretrial		Trial	
	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months	Number of Cases	Median Time Interval in Months
9TH	**28,079**	**8.3**	**10,616**	**6.6**	**15,385**	**9.3**	**1,601**	**14.9**	**477**	**25.8**
AK	317	9.0	109	6.8	204	9.3	1	-	3	-
AZ	2,000	11.8	789	9.1	1,114	11.0	45	20.7	52	31.0
CA,N	4,804	7.2	2,381	5.8	1,169	6.2	1,191	12.1	63	25.0
CA,E	2,196	10.7	887	7.8	1,255	11.0	26	20.0	28	34.5
CA,C	8,633	8.7	3,285	6.2	5,117	8.8	86	19.6	145	19.7
CA,S	1,831	6.4	170	2.8	1,630	6.3	8	-	23	25.5
HI	637	9.9	379	7.8	187	10.0	53	17.0	18	23.0
ID	456	12.8	37	4.0	369	12.4	40	23.0	10	31.0
MT	508	11.7	210	9.9	219	9.3	61	18.0	18	21.0
NV	1,547	10.0	761	9.7	742	10.5	28	9.0	16	31.0
OR	1,874	11.9	637	9.5	1,177	11.7	10	25.0	50	24.0
WA,E	519	9.5	166	5.2	311	9.5	28	14.0	14	22.0
WA,W	2,695	9.0	785	6.5	1,856	10.2	21	15.0	33	19.8
GUAM	32	6.0	9	-	20	5.0	2	-	1	-
NMI	30	8.8	11	7.0	15	8.4	1	-	3	-
10TH	**8,103**	**9.7**	**1,332**	**6.1**	**5,237**	**8.6**	**1,357**	**12.6**	**177**	**22.0**
CO	2,024	7.3	55	3.3	1,768	7.2	154	18.3	47	30.4
KS	1,149	9.1	362	7.9	640	8.3	119	18.1	28	24.0
NM	1,094	10.2	97	5.2	506	8.0	468	11.9	23	19.0
OK,N	727	11.3	77	4.5	614	11.5	21	18.0	15	20.0
OK,E	439	8.8	296	8.9	114	7.6	18	11.0	11	11.5
OK,W	1,225	8.9	305	4.5	492	8.3	403	11.3	25	16.0
UT	1,133	9.7	83	4.7	1,001	9.7	32	19.0	17	28.5
WY	312	11.4	57	4.7	102	83.5	142	10.3	11	15.0
11TH	**19,499**	**7.9**	**2,748**	**5.0**	**15,079**	**7.1**	**1,346**	**13.9**	**326**	**20.8**
AL,N	2,982	6.2	657	7.3	2,248	4.4	36	19.0	41	26.0
AL,M	809	10.5	222	7.3	493	10.6	65	17.6	29	17.0
AL,S	576	8.0	97	6.9	445	8.3	25	16.8	9	-
FL,N	811	7.1	212	5.8	580	7.5	9	-	10	16.0
FL,M	4,613	8.0	444	4.8	3,996	8.7	102	16.4	71	20.5
FL,S	5,429	5.0	311	2.0	4,687	5.2	350	8.6	81	18.3
GA,N	3,068	8.2	564	4.6	1,707	8.7	740	12.0	57	23.4
GA,M	680	11.2	133	8.2	530	11.8	2	-	15	22.0
GA,S	531	8.7	108	4.6	393	9.6	17	22.4	13	23.0

NOTE: MEDIAN TIME INTERVALS NOT COMPUTED WHEN FEWER THAN 10 CASES REPORTED. THIS TABLE EXCLUDES LAND CONDEMNATIONS, PRISONER PETITIONS, DEPORTATION REVIEWS, RECOVERY OF OVERPAYMENTS, AND ENFORCEMENT OF JUDGMENTS. FOR FISCAL YEARS PRIOR TO 2001, THIS TABLE INCLUDED DATA ON RECOVERY OF OVERPAYMENTS AND ENFORCEMENT OF JUDGMENTS.